

# **EXHIBIT 17**

James J. Farley

June 28, 2010

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IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

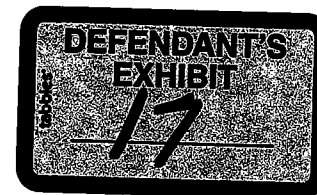
IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION

MDL NO. 1968

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The videotaped deposition of JAMES J. FARLEY taken by counsel for the Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC, pursuant to notice and by agreement of counsel, reported by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, on June 28, 2010, commencing at 9:10 a.m.

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APPEARANCES OF COUNSEL

FOR THE PLAINTIFFS:

PETER A. MILLER, ESQUIRE  
THE MILLER FIRM, LLC  
108 Railroad Avenue  
Orange, Virginia 22960  
(540) 672-4224  
pmiller@doctoratlaw.com

FOR THE DEFENDANTS, ACTAVIS TOTOWA, LLC, ACTAVIS, INC.,  
AND ACTAVIS ELIZABETH, LLC:

MICHAEL ANDERTON, ESQUIRE  
TUCKER, ELLIS & WEST, LLP  
1150 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475  
(216) 592-5000  
manderton@tuckerellis.com

FOR THE DEFENDANTS, MYLAN PHARMACEUTICALS, INC., MYLAN,  
INC., MYLAN BERTEK PHARMACEUTICALS, INC., AND UDL  
LABORATORIES, INC.:

ERICKA DOWNIE, ESQUIRE  
SHOOK, HARDY & BACON  
1155 F Street, N.W., Suite 200  
Washington, DC, 20004  
(202) 662-4864  
edownie@shb.com

ALSO PRESENT: Bill Kaska, Videographer

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16 attached to back of transcript.)

17 \* \* \* \* \*

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46	Article titled "Discovering the Cause of a Drug's Defect"	70
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103	E-mail from Mr. Farley to Ms. Barton dated 5/14/10 at 10:12 a.m.	321
104	E-mail from Mr. Farley to Ms. Barton dated 5/14/10 at 10:03 a.m.	321
105	E-mail from Mr. Farley to Ms. Barton dated 5/14/10 at 10:00 a.m.	321

1 THE VIDEOGRAPHER: Good morning. We're  
2 on record. It's 9:11 a.m. The date is June 28th,  
3 2010. This is the videotaped deposition of James  
4 J. Farley in the matter of Digitek Product  
5 Liability Litigation, United States District Court  
6 for the Southern District of West Virginia,  
7 Charleston Division, MDL No. 1968.

8 This deposition is being held at Embassy  
9 Suites held at 145 Mulberry Boulevard, Savannah,  
10 Georgia, 31322. The deposition was noticed by  
11 Matthew Moriarty of Tucker, Ellis & West, LLP,  
12 from Cleveland, Ohio.

13 My name is Bill Kaska for McKee Court  
14 Reporting here in Savannah, Georgia. The court  
15 reporter is Angela Garrett of McKee Court  
16 Reporting, 4849 Paulsen Street, Suite 304,  
17 Savannah, Georgia, 31405-4426.

18 Counsel, please state your appearances  
19 for the record, please.

20 MR. MILLER: My name is Pete Miller of  
21 The Miller Firm for Plaintiffs.

22 MS. DOWNIE: Ericka Downie from Shook,  
23 Hardy & Bacon on behalf of the Mylan defendants.

24 MR. ANDERTON: My name is Michael  
25 Anderton with Tucker, Ellis & West on behalf of

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1 the Actavis defendants.

2 THE VIDEOGRAPHER: Thank you. Madam  
3 court reporter, would you please the witness.

4 JAMES J. FARLEY

5 having been first duly sworn testified as follows:

6 THE VIDEOGRAPHER: Thank you. At your  
7 leisure.

8 MR. ANDERTON: Thank you.

9 - - - - -

10 DIRECT EXAMINATION

11 BY MR. ANDERTON:

12 Q Good morning, Mr. Farley.

13 A Good morning.

14 Q We met a few moments ago. My name is  
15 Michael Anderton. I am with Tucker, Ellis & West in  
16 Cleveland. And I am here on behalf of the Actavis  
17 defendants in the Digitek litigation.

18 Will you just spell your name and provide your  
19 home address for the record, please.

20 A First name James, J-A-M-E-S, I usually use  
21 my middle initial, J. for Joseph, last name, Farley,  
22 F-A-R-L-E-Y. Home address is in Savannah. It's 101  
23 Captain John's Drive, Savannah, 31410.

24 Q And do you have a business address as  
25 well?

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1                   A    That is my business address. I have a  
2 home business.

3                   Q    And what business do you run out of  
4 your -- do you work for out of your home?

5                   A    I do chemistry and pharmaceutical  
6 consulting.

7                   Q    Do you have a name? Is there a name for  
8 the company that you work for or operate or own?

9                   A    I call my company -- I am my company --  
10 Cardinal Consulting and Training. And in this case I'm  
11 contracted out to do work for Smart Consulting Group in  
12 West Chester, Pennsylvania.

13                  Q    So the Cardinal Consulting and Training,  
14 do I understand correctly that you are the sole employee  
15 of that company?

16                  A    I'm everything.

17                  Q    Everything.

18                  A    That is me.

19                  Q    Okay. And you say you're contracted out  
20 by Smart Consulting in Pennsylvania?

21                  A    West Chester, Pennsylvania, suburb of  
22 Philadelphia.

23                  Q    How did that relationship come to be in  
24 existence, your current relationship with Smart  
25 Consulting in the context of this litigation?



1           A    I've known Nigel Smart, Dr. Nigel Smart,  
2   for over a dozen years now and we work together on  
3   projects. And most recently Nigel and his wife, Denise,  
4   formed their own business. By recently, the last half a  
5   dozen years, somewhere thereabouts.

6           And he will call people he knows on certain  
7   projects and contract with them and say, here's a  
8   project, would you do this aspect of the project for me.  
9   That's what I mean by contract out.

10          Q    Okay. And is that how your relationship  
11   with -- or how your involvement in this litigation came  
12   to be? Did he contact you and ask you to be involved in  
13   some aspect of this litigation?

14          A    Yes.

15          Q    When did that happen?

16          A    I'd have to check the records for initial  
17   contact, but it was around the end of last year or  
18   beginning of this year.

19          Q    End of 2009, beginning of 2010?

20          A    Yes.

21          Q    After -- is it Dr. Smart?

22          A    Dr. Nigel Smart.

23          Q    After Dr. Smart contacted you did you  
24   ultimately come to have direct contact with counsel for  
25   the plaintiffs in this litigation?

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1 A Yes.

2 Q And how did that come to be? Did  
3 Dr. Smart put you in touch with them? Did they contact  
4 you directly? How did that happen?

5 A He did what is pretty much typical in  
6 situations like this. He said a gentleman named Peter  
7 Miller will be contacting you, I've given you his number  
8 and he will call you to discuss the project with you.  
9 And it was either the same day or the following day that  
10 Pete Miller did call me and we discussed the project.

11 Q Okay. And he said gentleman?

12 A I'm sorry?

13 Q Never mind. You're not a medical doctor,  
14 are you?

15 A No.

16 Q Your testimony a moment ago was that you  
17 provide consulting service on I think chemistry and what  
18 was the second category?

19 A Pharmaceuticals, general pharmaceuticals,  
20 a lot of FDA regulatory.

21 Q I want to find out a little bit more about  
22 that. When you say pharmaceuticals and then you expand  
23 that a little bit by saying a lot of FDA regulatory, can  
24 you give me more detail?

25 What does -- what type of consulting do you

1 do? What do you consult in with respect to  
2 pharmaceuticals as you've described it?

3 A I'll go back to 1996 when I resigned my  
4 position at the FDA in Philadelphia.

5 Q Okay.

6 A And I formed Cardinal Consulting, which  
7 was just give me the name and saying I'm going to be a  
8 consultant. And initially it was analytical methods and  
9 analytical procedures because much of that was what I  
10 did.

11 However, in my eight years at FDA, during  
12 which time they promoted me to be director of the  
13 science branch of the Philadelphia district where 30  
14 chemists were in my employ, I -- since I had  
15 participated in FDA inspections, since I had to assign  
16 chemists to FDA inspections and since I had to review  
17 Establishment Inspection Reports, called EIRs, and the  
18 FDA 483s and review and in some cases sign warning  
19 letters, I included that in my repertoire of services.

20 Q So -- I mean, you just described how you  
21 came to kind of provide consulting services and how you  
22 expanded it beyond analytical methods consulting.

23 Can you give me just a little more detail just  
24 about exactly what you -- what you do in a typical  
25 consulting -- or what services you will offer? I

1 should -- let's start -- let's back that up.

2 A Uh-huh.

3 Q First tell me in more substance when you  
4 say you consult with respect to analytical methods or  
5 with respect to FDA regulatory, what types of activities  
6 do you actually perform?

7 A Uh-huh. With regard to analytical test  
8 procedures, those test procedures which are within my  
9 area of expertise, I may design it for a pharmaceutical  
10 firm or I may review one that they have and add, delete  
11 or modify as necessary or I may review one that they're  
12 having a problem with or I may visit a contract testing  
13 firm and look at their methods.

14 If the big firm wants to contract out they  
15 might say, Jim, go look them over and tell us that  
16 they're okay. So I could do any of those things  
17 relevant to analytical procedures. That would extend  
18 over to Good Manufacturing Practices, GMPs.

19 A lot of times you see it with the little c  
20 for current in front of it, but GMP is the normal term.  
21 And that would involve everything from raw material  
22 coming in to a firm, how is it tested, who tests it,  
23 what procedures, standard operating procedures, SOPs,  
24 are in place or are needed, how are -- how are these  
25 materials transported to manufacturing, what in-process

1 tests are done in manufacturing, how about the  
2 qualifications of people all along the way,  
3 qualifications of training, up to and including finished  
4 goods testing, which is also called release testing  
5 because you're releasing the product to the public. So  
6 that's all the testing.

7 But there's more to it. You have the  
8 calibrations. You have your systems. You have the  
9 entire system, not just of the test. The test is part  
10 of the system.

11 It's the training of the individuals, the  
12 assignments given to the proper individuals, their  
13 experience with it. I'll pause here and look to you  
14 for -- what more do you want?

15 Q I think that's enough detail. You've  
16 given me a --

17 A Okay.

18 Q -- better understanding of what you do  
19 when you provide pharmaceutical consulting. And I  
20 should pause briefly, Mr. Farley, and go over a quick  
21 ground rule that I should have incorporated into the  
22 examination at the very -- you know, at the very  
23 beginning. And I apologize.

24 But if I ask you a question today and you  
25 don't understand it, if I say it poorly, if it just

1 doesn't make sense, if for whatever reason you don't  
2 understand it, will you please ask me to say it  
3 differently or ask it differently or to rephrase it  
4 somehow?

5 A Yes, I will.

6 Q Okay. And if you answer a question that I  
7 ask you and you don't ask me to rephrase it, I will  
8 assume that you understood it as asked and that you  
9 answered it with an understanding of it as I asked it.

10 Is that -- is that fair?

11 A That's fair. I understand what you're  
12 saying now.

13 Q Excellent. So the consulting services  
14 that you just described in reasonably significant  
15 detail -- and I'm talking about the -- not the  
16 analytical method consulting, but the consulting  
17 services that you -- the pharmaceutical, the regulatory,  
18 how much of your current workload at Cardinal is divided  
19 between regulatory consulting and the analytical methods  
20 consulting?

21 A The analytical methods consulting is part  
22 of the regulatory since the methods must be designed and  
23 validated in order to be submitted to FDA. So I'm going  
24 to take my time and try to answer your question. But  
25 since regulatory includes these methods --

1 Q Right.

2 A -- at any given time these days it could  
3 be anywhere from 10 to 40 percent. It depends on the  
4 individual project.

5 Q So do I understand that you would say that  
6 60 percent or so of your current consulting work focuses  
7 on the analytical methods, purely the analytical methods  
8 review and analysis?

9 A No, no. That's not what I meant.

10 Q Okay. Then I misunderstood.

11 A I'll reword it.

12 Q Okay.

13 A Taking analytical methods development or  
14 review or evaluation, anything related to analytical  
15 methods as part of regulatory, that percentage of the  
16 analytical methods work that is part of my overall  
17 regulatory business can vary from 10 to 40 percent of  
18 work with time involved at any given time.

19 Q Okay. Okay.

20 A Is that --

21 Q All right. So you consider it all  
22 regulatory with 10 to 40 percent being the analytical  
23 methods type analysis?

24 A Yes.

25 Q Okay. And your clients then typically are

1 pharmaceutical manufacturers or companies who are  
2 somehow involved in the pharmaceutical industry?

3 A Yes.

4 Q Have you been -- well, when you're hired  
5 by a company to engage in regulatory consulting as  
6 you've described it, tell me how you would kind of  
7 approach that engagement.

8 Tell me the steps that you would undertake in  
9 a typical engagement if somebody is hiring you -- let's  
10 say, for example, a company hires you to determine  
11 regulatory compliance, whether they are in compliance  
12 with Good Manufacturing Practices.

13 How would you undertake that engagement?

14 A What I would do first is define the scope  
15 of work, what do you want me to do, because the way that  
16 is presented, get us in compliance, that could range  
17 anywhere from two days to two years.

18 So as with any project in any field, define  
19 the scope of work so that you're doing the proper thing  
20 for the customer. The reason I say that is a customer  
21 might say, I have another consultant doing computer  
22 validation. Good. You don't want me to go near your  
23 computer validation.

24 But I want to look and say, all right, what do  
25 you want me to do? Analytical methods. How many? Let



1 me see which ones they are. Do you need any developed?  
2 Do you want me to review them? What do you want me to  
3 do? Then I will look at them. And it could be -- and  
4 I'm making this up to answer your question right now.

5 Q Understood.

6 A It might be, I've got to be at your firm  
7 and watch this being done. You have the method. It's  
8 not working out. I have to be there to see -- meet the  
9 analysts and see who's doing it. Vastly different in  
10 time and money than sending it as an e-mail attachment  
11 and having me read it.

12 Q Okay.

13 A So I want to look at that and then put a  
14 proposal to the client as to the job as I perceive it is  
15 review the following methods. I will come to your  
16 facility for two days and work with your analytical  
17 chemists. Then I will go back to my home base and write  
18 a report.

19 In some cases it might just be, we'll send you  
20 the methods and tell us if they're in the proper format.  
21 So getting to your original question, I would first  
22 define the scope of work and then give them a proposal  
23 as to how I would go about it to get their authorization  
24 for it. And then we proceed from there.

25 Q And once you -- and once you provided them

1 the proposal and defined the scope of the project as  
2 you've described it, if you were asked by a company to  
3 determine whether a certain product had been  
4 manufactured and released in compliance with Good  
5 Manufacturing Practices, would that involve document  
6 review?

7 A Yes.

8 Q What types of documents would you review  
9 in the context of that analysis?

10 A Could I have that question again?

11 Q Yes. I asked you if you would review  
12 documents in order to determine whether a certain  
13 product had been manufactured in compliance with Good  
14 Manufacturing Practices and you said yes.

15 A Yes.

16 Q What types of documents would you review  
17 to undertake that analysis and advise the company  
18 whether they then -- whether that product had been  
19 manufactured in compliance with Good Manufacturing  
20 Practices?

21 MR. MILLER: And I'm going to object.

22 It's an incomplete hypothetical. But it's okay to  
23 answer.

24 A For a thorough answer to your question, or  
25 a thorough part of -- again, defining the work, I would

1 say to the client, well, what I want to do, I want to  
2 see -- are you having any problems anywhere? Are you  
3 having problems with new analytical chemists that are  
4 having problems with their answers? I try to define it  
5 more specifically.

6 And -- but typically it involves going back to  
7 all the procedures from raw materials coming in, in  
8 process materials as it is being produced and the  
9 testing that's associated with it and the finished goods  
10 released.

11 I want to see the whole workload from raw  
12 materials in to finished product out. That's what I  
13 want to see. And I also want to see -- and it's very  
14 important -- the training records of the people involved  
15 in doing it to make sure they're qualified.

16 Q So you want to see -- if I understand  
17 correctly, you want to see all documents associated with  
18 production of that product?

19 A Yes, I do.

20 Q And you want -- and then you review them  
21 and develop your opinion as to whether GMPs have been  
22 complied with or not?

23 A Yes, I would. I want to put it in a  
24 proposal first --

25 Q Understood.

1           A    -- so that the client knows the time and  
2   their money involved and they don't try to get me to  
3   short-cut something. So you have to be thorough in  
4   things. And I want them to know the degree of  
5   thoroughness and the amount of time and energy it will  
6   take to do it.

7           Q    I understand. But in order to be thorough  
8   and to properly advise that client about whether that  
9   product had been manufactured and released in compliance  
10   with Good Manufacturing Practices, you'd tell them up  
11   front so that they wouldn't be surprised at how much  
12   time and cost might be involved that you need to require  
13   all of the records you've just described -- or I'm  
14   sorry -- you need to review all of the records that  
15   you've just described. You'd tell them that up front,  
16   correct?

17          A    Yes, I would. And it wouldn't surprise  
18   them. They usually expect me to say that.

19          Q    Okay. What if they didn't want you to  
20   review those records? Could you do the analysis that  
21   I've just described?

22          A    It is quite likely that I could not and I  
23   would not accept the project.

24          Q    Okay.

25          A    I might just say, you don't want me, you

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1 want someone else, I can't do it under your constraints.

2 Q Okay. Have you ever been deposed before?

3 A Yes.

4 Q How many times?

5 A In the last four years twice.

6 Q Tell me about those two times.

7 A Can I refer to my report?

8 Q Actually -- to your report?

9 A It's --

10 Q Your expert report?

11 A The depositions are in the report.

12 Q Yeah. Let's do this a little differently,  
13 though, because I've actually got that marked as an  
14 exhibit, so -- and if you can -- you can go ahead and  
15 put those off to the side. I'm going to review those  
16 when we get a break. But I --

17 A All right. If you have the two cases --

18 Q I do.

19 A -- that will be fine.

20 Q Okay. So, Mr. Farley, I have handed you a  
21 copy of a document. And we've pre-marked our exhibits.  
22 You might have heard a little bit of that exchange as we  
23 were getting ready to go on the record this morning. So  
24 the numbers aren't going to go sequentially necessarily.  
25 If we mark new exhibits we'll make them somehow

1 sequential. But this document has been premarked as  
2 Exhibit 45.

3 A Can I write on this? It's dark.

4 MR. MILLER: No.

5 Q No, you can't.

6 A I'll just remember 45. I'll remember it.

7 Q Yeah. Well, we'll remember that it's your  
8 report. Will you take a moment just to look at that  
9 document and confirm that it is the report you were  
10 referring to a moment ago, your expert report in this  
11 case? And I will tell you in advance that we have taken  
12 your CV off the back. We'll make that a separate  
13 exhibit.

14 A That's my report.

15 Q Okay. So Exhibit 45 is the report that  
16 you prepared I assume at the request of Plaintiffs'  
17 counsel in this Digitek litigation and it's the report  
18 you were referring to when I asked you to identify  
19 the -- or you were about to review and refer to when I  
20 asked you to identify the times you've been deposed in  
21 the last couple of years, correct?

22 A Yes.

23 Q Will you -- so let's go back to my  
24 question. What are the times you've been deposed? You  
25 said you've been deposed twice.

1 A In the last two years.

2 Q Okay.

3 A I believe I was several years ago, but  
4 it's vague in my memory. But these are the more recent  
5 ones and they're on page 4 under background.

6 Q Okay. And so I see two cases listed here.  
7 One it looks like Chanin versus Desert Shadow Endoscopy  
8 Center. Tell me about that. What was the nature of  
9 your involvement in that litigation?

10 A I heard the question. I'm trying to think  
11 of --

12 Q Take your time.

13 A I'm posing my answer so I know where to  
14 start and get right to the answer.

15 Q I appreciate that.

16 A There was -- there are a couple of  
17 endoscopy clinics all under the same ownership in Las  
18 Vegas. And there were a combination of factors. They  
19 were multi-dosing Propofol when they would sedate the  
20 patients for endoscopies and other such procedures.

21 And they were accused of -- I say -- I'm  
22 pausing about the word alleged. It's been proven. So  
23 I'll knock out the word allege.

24 They were taking Propofol from a large  
25 container, giving it to one patient and taking a little

1 more, giving it to that patient and then taking some and  
2 giving it to another patient. In the course of doing  
3 that several patients contracted hepatitis.

4 Teva and Baxter, the manufacturer and  
5 distributors, were involved in that they were selling  
6 the large units where a purchaser like an endoscopy  
7 clinic could get a discount price and were selling it to  
8 a clinic known that they only needed the little vials.

9 And while I'm pausing, because once I did my  
10 work I'm speculating what came after, but the court  
11 judged that, yes --

12 Q And I apologize for kind of cutting you  
13 off. Can you just describe for me what your involvement  
14 in the case was? Generally what were you engaged to  
15 review and what was the general subject of your  
16 opinions?

17 A Thank you for that. I was pausing because  
18 I wasn't sure --

19 Q Yeah, yeah.

20 A -- this or that what the Court said when I  
21 wasn't there.

22 Q At least initially I'd only like to hear  
23 your involvement and what your opinions were. And then  
24 I'll decide whether I want to ask more.

25 A That's what I can answer most



1 intelligently.

2 Q Okay. Excellent.

3 A My involvement was looking at the labeling  
4 of the Propofol and the manufacturing of the Propofol  
5 and rendering an opinion in that regard. Does that  
6 answer your question?

7 Q It absolutely does. And does that mean  
8 that your involvement in that case did not touch on --  
9 you weren't asked to give an opinion about regulatory or  
10 GMP compliance in any aspect?

11 A With regard to the labeling.

12 Q Not with respect to production or  
13 manufacturing or analytical or laboratory related GMPs?

14 A Not to any major degree.

15 Q Okay. The next case listed here, Olson  
16 versus Septodont, tell me about your -- again, what was  
17 your involvement? What were you engaged to give an  
18 opinion on in that case?

19 A In one respect it was a similar case. It  
20 just happened to be. A lady in the Tacoma, Washington  
21 area who was a dental patient was given Septadine by her  
22 dentist. And the reason for that is to numb the gum  
23 area while the dentist did his work.

24 But she -- I'll use the word overdosed, but  
25 I'll put it in quotes, because I don't want to use

1 that -- too much was given. And she -- it ruined her  
2 nerve. Her face sagged. She has trouble talking. It  
3 was irreversible what happened to her. And we looked at  
4 manufacturer, industry and the labeling aspects of it,  
5 including directions.

6 Q And when you say we, do you mean you?

7 A Oh, me. There were no other chemists to  
8 my knowledge. At least I didn't meet any. We meaning  
9 my client, the lawyer.

10 Q So what type of compliance issues did you  
11 give an opinion about in that case? Do you remember?

12 A Labeling plus the responsibilities of a  
13 generic manufacturer.

14 Q With respect to what?

15 A With respect to labeling, extra labeling,  
16 putting warnings on, giving notices, keeping track of  
17 who buys it.

18 Q Okay. So that was -- your involvement in  
19 that case was fairly narrowly limited to labeling and  
20 related issues?

21 A Yes, uh-huh.

22 Q Let's go back to your time at the FDA.  
23 You were there from 1989 until 1996? Does that sound  
24 right?

25 A Yes.

1 Q And you said -- your background -- well,  
2 first things first. Your background, your educational  
3 background, is in chemistry, correct?

4 A Primarily. I have a master's degree in  
5 physio-chemistry, but then I went on to get an MBA in  
6 financing and marketing.

7 Q Okay. And when you were at the FDA you  
8 were initially hired as an analytical chemist?

9 A Yes.

10 Q How long were you in that position?

11 A By title, about three years; by  
12 assignment, about one year. The district director of  
13 the Philadelphia district and the regional director of I  
14 think four districts at that time, Baltimore -- it's  
15 been rearranged. It's vague now.

16 But the regional director knew that I had  
17 experience in the pharmaceutical industry. And they had  
18 some things they wanted me to help out with, like  
19 getting the samples out more on time and looking at some  
20 things that -- I'm pausing because I don't want to say  
21 anything negative about government employees.

22 But there were some mindsets there of this is  
23 the way we've always done it. And as one of my bosses  
24 said to me, you're breathing a breath of fresh air in  
25 here letting us get done what we want to get done.

1                   And just helping them like, why are you doing  
2   this when you should do this, little management  
3   assistance but I was still classified as an analyst.  
4   But I would travel to the Baltimore lab and the  
5   Cincinnati lab as in effect the person who was sent by  
6   the regional director to work with them to improve their  
7   procedures.

8                   Q   Does that mean that you were providing  
9   guidance or insight with respect to what I'll  
10   characterize as efficiency issues?

11                  A   Yes.

12                  Q   Okay. And you say that started after  
13   about a year?

14                  A   Yes.

15                  Q   It lasted how long?

16                  A   Up to and including when they promoted me  
17   to be director of the science branch, which is in effect  
18   the laboratory director.

19                  Q   Okay. And that was after three years,  
20   after you've been at the FDA for three years?

21                  A   Three years, three and a half. Three.  
22   Just say three.

23                  Q   Okay. You were there a total of about  
24   eight years?

25                  A   About eight.

1           Q    When you became director of the lab I take  
2   it that means you jumped over a couple levels of  
3   supervisors to go from an analyst position with those  
4   kind of efficiency responsibilities directly to the  
5   director of the lab.

6           Does that mean you jumped over a couple of  
7   levels?

8           A    Yes.   Some people I worked for were then  
9   working for me.

10          Q    That's always fun.

11          A    It was.

12          Q    Tell me what you did as director of the  
13   lab.

14          A    With 30 chemists in the lab I was  
15   responsible for all of their functions.   I worked  
16   through two supervisors.   There were two supervisors who  
17   reported to me.   But I knew everyone in the lab on a  
18   first name basis.

19                But they had to get their analytical work  
20   done, their analytical work of samples that were taken  
21   and brought in from pharmaceutical firms.   They had to  
22   do that.

23                They did some analytical methods development  
24   and they had to accompany the inspectors on the  
25   inspections.   An inspector is an investigator, is a

1 consumer safety officer. They were all the same.

2 Consumer safety officer is their designation, CSO, but  
3 we called them inspectors or investigators.

4 When they go on an inspection they want one or  
5 more chemists with them to be more knowledgeable about  
6 the scientific aspects of their investigation. An  
7 investigator -- I've known investigators that had Ph.D.s  
8 in science and I've known others that had 30 credits in  
9 science.

10 The ones that -- the ones in inspections, they  
11 know what they're going to be looking at. And if they  
12 don't know initially they see when they get there and  
13 they'll call and say, I need a chemist who's  
14 knowledgeable about this or this. Okay, send them up.

15 So participating in inspections, assigning the  
16 proper chemist and doing the scheduling to make sure  
17 that the work flow in the lab is always done. This was  
18 all part of the job of running the lab.

19 Q Okay. So typically you weren't the person  
20 who was in the field involved in FDA inspection,  
21 correct?

22 A I was as an analyst accompanying  
23 investigators in the scenario I just mentioned.

24 Q Well -- okay. So as an analyst you mean  
25 during that first year of employment before you started

1 traveling to other labs and counseling the FDA regional  
2 offices or district offices on efficiency?

3 A And during the second and third year.  
4 When needed, when they needed me.

5 Q How often?

6 A It's tough to pick an average. You might  
7 go two in a row and then none for a couple months. It's  
8 difficult. If I said a few, would that be too vague?

9 Q Well, if you give me a better sense of a  
10 few. You were in that position for -- as an analyst --  
11 let's break this down a little bit. As an analysis you  
12 were in that position for three years.

13 A Yes.

14 Q During those three years did you  
15 participate -- and by participate I mean go out and  
16 actually -- where you were actually on site, not  
17 involved in scheduling and deciding who goes and things  
18 like that, but where you were actually on site how many  
19 inspections would you say you were involved with during  
20 those three years?

21 A I'm drawing on my memory now.

22 Q All I can ask you is to the best of your  
23 recollection.

24 A One quarterly.

25 Q One quarterly. So that's perhaps a dozen

1 in three years?

2 A Yes.

3 Q And you weren't necessarily on the  
4 premises for each and every day of all of those  
5 inspections, right? You were there as needed?

6 A Generally as needed. The inspectors feel  
7 comfortable having you there every day, but the workload  
8 doesn't always permit it. They really feel comfortable  
9 having one or two scientists around. But you get there.  
10 You do your job. What do you want me to look at? What  
11 do you want me to evaluate? And then you -- that's it.

12 Q When you became director, so during that  
13 last five years, how many inspections were you involved  
14 with by actually -- and by involved I mean actually on  
15 the premises during the inspection.

16 A I wasn't assigned directly because it  
17 wasn't my primary area of responsibility. However,  
18 in -- I should say the Philadelphia district included  
19 Pennsylvania and Delaware. And the laboratory covered  
20 Jersey because they didn't have a lab.

21 I would not be assigned to go on any of them.  
22 But I would on occasion say, I'm going to drop in on  
23 such and such a day and just walk through with you. And  
24 that might be to Merck or what was then SmithKline  
25 Beecham -- it's now GlaxoSmithKline -- just to make sure



1 that everything was going along well.

2 Q So participating in investigations or  
3 inspections in the field was not something you did  
4 regularly?

5 A You could say that, yes.

6 Q How many -- you mentioned earlier and I  
7 believe your report references it as well. How many  
8 warning letters did you issue while you were employed by  
9 the FDA?

10 A I signed?

11 Q Well, let's break that down a little bit.  
12 How many -- let's ask that question first. How many  
13 warning letters did you actually sign?

14 A I might have only actually signed one. I  
15 was involved in the input of various -- our district  
16 director signs the warning letter.

17 Q How many -- well, did you draft that one  
18 warning letter that you signed?

19 A No. It's drafted by the investigation  
20 staff and then brought to you and you -- that is a  
21 document that before you sign you read every word. It's  
22 not a glance at and sign and get it off your desk type  
23 of document, not to imply that the federal government  
24 has any like that. But you read every word because of  
25 the severity of it.

1 Q Well, but there's a difference between  
2 reading it and having an understanding of it and  
3 actually drafting and having input, correct?

4 A Yes.

5 Q And as director of the lab you weren't  
6 responsible for drafting and developing warning letters,  
7 were you?

8 A No.

9 Q And in fact, the one that you signed you  
10 signed only because you were in some sort of acting  
11 capacity outside your lab director position?

12 A It was while I was still a lab director,  
13 but when the boss would either be on some -- maybe down  
14 at headquarters for a meeting or on vacation he might  
15 just say, Jim, take my place as district director for  
16 this week. And I might say, well, Boss, what have you  
17 got coming in? And he might give me a rundown of what  
18 to expect.

19 Q So that made you essentially acting  
20 district director?

21 A Yes.

22 Q And that's why you signed that single  
23 warning letter?

24 A Yes.

25 MR. ANDERTON: Are you sharing one with

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1 him?

2 MR. MILLER: It looks like I am.

3 MR. ANDERTON: Okay.

4 THE WITNESS: Okay.

5 MR. ANDERTON: Actually do you need one  
6 while we're --

7 THE COURT REPORTER: Not while we're  
8 doing this.

9 MR. ANDERTON: Okay. Thank you. So the  
10 ones that we give Mr. Farley can go to Angela.

11 BY MR. ANDERTON:

12 Q Mr. Farley, I've handed you a document.  
13 And I know the exhibit stickers perhaps are difficult to  
14 read. But it has been marked as Defendants' Exhibit 44.

15 A Yes.

16 Q Can you just take a moment to review that  
17 document, please.

18 A That's me.

19 Q Okay. Is that an accurate copy of your  
20 CV?

21 A Yes, it is.

22 Q It's the one that you actually attached as  
23 Attachment A to the report that you prepared in this  
24 case, correct?

25 A Yes.

1 Q I think I asked you this earlier. You're  
2 not a medical doctor, correct?

3 A I'm not a medical doctor.

4 Q All right. Is it accurate to say that  
5 your expert opinions in this case are limited to  
6 opinions about whether Actavis was in regulatory  
7 compliance with Good Manufacturing Practices?

8 A Yes.

9 Q You're not offering any opinion about how  
10 any -- whether -- let me start that over.

11 You're not offering any opinion about whether  
12 any specific consumer or patient got or received and  
13 took product that was defective?

14 MR. MILLER: Object to form of the  
15 question.

16 A I'm not sure I'm understanding your  
17 question the way it's worded.

18 Q Let me see if I can ask it more clearly.  
19 Is it true that you're not offering an expert opinion  
20 about whether a patient in the market received a  
21 defective Digitek tablet?

22 A I wouldn't know if a patient in the market  
23 received a defective tablet unless I was told or saw  
24 data. Is that --

25 Q Well, so then -- but you need to answer my

1 question, Mr. Farley. You're not offering an opinion in  
2 this case about whether any consumer received a  
3 defective Digitek tablet, correct?

4 MR. MILLER: Object to the form of the  
5 question.

6 A I'm thinking the way it's worded, I read  
7 that a consumer did, but I don't have an opinion on it.

8 Q Well, so I need to be clear then. You're  
9 not offering an opinion on that subject, correct?

10 A As to whether a person taking a particular  
11 medication received it or not?

12 Q Correct.

13 A I have no idea who took it.

14 Q Okay. And you're also not offering any  
15 opinion about how specific patients react to specific  
16 doses of Digitek, are you?

17 A Not a professional or an expert opinion.  
18 There are things you know about certain drugs from being  
19 in the industry 40 or 45 or more years, but not who  
20 would be prescribed. I don't prescribe.

21 Q Well, all right. Again, I want to make  
22 clear. In the context of this case and this litigation  
23 you're not offering any opinions about how any patient  
24 reacts to a specific dose of Digitek; is that correct?

25 A Not with regard to a patient, no.

1 Q Okay. Have you ever been a defendant in a  
2 lawsuit?

3 A I'm pausing. I should know, like would  
4 know, but I'm -- in order to answer your question  
5 correctly, no, I have not.

6 Q Have you ever actually testified -- we've  
7 talked about the times you've been deposed. Have you  
8 ever actually testified in court?

9 A Not as a consultant. When I was with the  
10 FDA -- and that was not a case such as this. That was  
11 an EEO case since I was chairman of equal opportunity at  
12 the same time.

13 Q So it was an employment case, not a  
14 regulatory and -- not a case that had anything to do  
15 with regulatory compliance?

16 A Correct.

17 Q Any other times? Have you ever testified  
18 any other times?

19 A I did not. They all settled. I would be  
20 glad to do it, but they just -- the attorney, my client,  
21 would contact me and say, we settled the case, send the  
22 final bill. And that was it.

23 Q How did you prepare for this deposition?

24 A During -- off and on. During the last  
25 several weeks I would receive documents from Miller Law

1 Firm, specifically Pete Miller. And I would review  
2 them. And when I received notice about a week ago that  
3 this deposition would be today I said, how about if I  
4 review my reviews. And that's what I did.

5 Q And the documents that you said you  
6 reviewed over the last several weeks, what documents  
7 were those? Well, let me make that question clearer.

8 The documents that you said you received from  
9 the Miller Firm over the last several weeks, I believe  
10 is your terminology, what documents were those?

11 A They would include EIRs, Establishment  
12 Inspection Reports; 483s; warning letters; a revised  
13 warning letter; various documents within a firm; charts  
14 of regulatory activity; some current Actavis  
15 correspondence, internal and to the FDA; the request for  
16 consent decree; the consent decree itself.

17 They would all come in binders and a binder  
18 might contain a variety of document -- would contain a  
19 variety of documents. That's what.

20 Q When did you start receiving those  
21 documents, those binders of documents?

22 A I believe the first binder arrived in  
23 January. Then -- I reported on that and then there was  
24 a space in time and then another binder arrived in  
25 April.

1           Q    When you say then you reported on that  
2 first binder, what do you mean by you reported on that?

3           A    Wrote a brief report on my evaluation --

4           Q    Of that first binder?

5           A    -- of the contents of the first binder.

6    Yes.

7           Q    And what became of that brief report  
8 regarding the contents of that first binder?

9           A    I sent it to Pete Miller at Miller Law  
10 Firm.

11          Q    Do you have that first report on that  
12 first binder with you today?

13          A    I've got it on a thumb drive.

14          Q    Thumb drive. I was --

15          A    There was only so much I could fit in  
16 suitcases.

17          Q    And having read one of your prior  
18 deposition transcripts I know that you use the thumb  
19 drive. So that's on my list of things to ask you today,  
20 believe it or not.

21               We will definitely want to take the thumb  
22 drive and -- or somehow get the documents that are on  
23 that thumb drive that relate to this litigation in our  
24 possession. Okay?

25          A    Yes.



1 Q And in fact, it occurs to me I might want  
2 to see those today before we leave so that I can  
3 determine whether I want to ask you any questions about  
4 that.

5 A Yes.

6 Q So we'll work on that during the break  
7 somehow. Okay?

8 A Fine.

9 Q How many binders total did you receive  
10 from -- well, did you receive documents from anyone  
11 except the Miller Firm?

12 A I'm thinking. I heard your question.

13 Q Take your time.

14 A I'm thinking to give you an accurate yes  
15 or no on that.

16 Q I appreciate that very much.

17 A No, only the Miller Firm.

18 Q How many binders or -- how many times did  
19 you receive documents? Perhaps they weren't always in  
20 binders. How many -- how many shipments of documents  
21 did you receive from the Miller Firm?

22 A A total of five binders. There may have  
23 been two in one shipment. So my answer is it's  
24 definitely binders and likely to be four shipments.

25 Q Okay. Are the documents -- and did you

1 review all of the documents in those binders?

2 A Yes.

3 Q Are the documents you reviewed -- now, I  
4 asked you initially what you did to prepare for this  
5 deposition and I think we've kind of transitioned to  
6 what you did to prepare your report.

7 Is that a fair characterization of what we're  
8 describing now when we're talking about all of these  
9 binders received over what sounds like a five- or  
10 six-month period?

11 A Yes. That was -- I had the initial binder  
12 and then wrote a report on -- in February, I believe  
13 February 5th. And then later on more binders arrived.  
14 So I reviewed them and I wrote another report.

15 Q So you wrote -- did you write a report in  
16 response to each binder that you received?

17 A Not in response to each binder. I just in  
18 effect kept building up the original report.

19 Q Okay.

20 A I took the original report and just  
21 expanded the table. But each document has an individual  
22 review electronic file on my thumb drive.

23 Q Okay. So each document then has a -- I  
24 take it then that there are documents on that thumb  
25 drive that reflect your specific analysis and perhaps

1 comments regarding each document that you reviewed?

2 A All 93 of the -- all -- some were  
3 duplicates in title but had different redactions.

4 Q Okay.

5 A So there may have been roughly 80 to 85  
6 different documents. I had a total of 93. And in some  
7 cases here's a 483, here's a 483 I received two months  
8 ago, but there are different redactions. I can see more  
9 or less. So I'm saying 93 documents and -- 90 to 93.  
10 But each one is a file on the thumb drive in my pocket.

11 Q Okay. Well, that's going to speak to the  
12 viability of my reviewing those documents on a break  
13 today. And unfortunately it may also speak to whether  
14 we have to reconvene, leave the deposition open and have  
15 a second session. But those are decisions that we'll  
16 make as we kind of move through the process.

17 MR. MILLER: While we're on that topic, I  
18 brought a hard copy of everything he's talking  
19 about and you're certainly more than welcome to  
20 take a look at mine.

21 And although it sounds quite lengthy,  
22 it's not as lengthy as you would think. I wasn't  
23 anticipating the thumb drive. So I brought a copy  
24 for me.

25 So being the great guy that I am I'm

1 going to offer up the copy that I brought so you  
2 can read them at lunch in hopes of possibly  
3 wrapping this up.

4 MR. ANDERTON: Okay. Well, I appreciate  
5 that and we'll certainly take a -- at least an  
6 initial run through it and we'll decide from  
7 there.

8 I mean, I apologize if there's an  
9 inconvenience involved, Mr. Farley, but I hope you  
10 understand, you know, we have to see what's out  
11 there and then react accordingly.

12 THE WITNESS: There's no inconvenience.  
13 That's what we're here for and that's why I  
14 brought the little computer and the thumb drive.

15 MR. ANDERTON: I'm actually talking about  
16 the possibility of reconvening and having at least  
17 a partial second session, you know, if I decide  
18 that we can't get it all done today and if we need  
19 a little time to review those documents. But  
20 we'll make those decisions as we move through the  
21 process.

22 THE WITNESS: Your choice.

23 MR. ANDERTON: Excellent.

24 BY MR. ANDERTON:

25 Q So then you said you kept building up the

1 report. Does that mean that you would characterize each  
2 of these reports as drafts that led up to the final  
3 report you issued in this case?

4 A No. They weren't intended to be drafts.  
5 I might prepare a report and save it as a file on my  
6 thumb drive and the C drive, the C drive of my PC in my  
7 home office.

8 Q Right.

9 A And then I'd review it a couple days later  
10 and I might say, oh, well, I looked at more references  
11 than that, I looked at the Physicians' Desk Reference, I  
12 looked at this. And I would, upon thinking about it,  
13 add more to it.

14 But then I felt I can't keep it as the same  
15 document. I added to it for the reason I just  
16 mentioned. I'll save it as a new document. And I  
17 usually did that just by the date.

18 Q Okay. Okay. The 90 or so documents that  
19 you said you reviewed, some duplicates or others with  
20 different redactions and such, are all of those  
21 documents listed in your report as documents that you  
22 reviewed?

23 A Yes, they are.

24 Q Are there any documents that you reviewed  
25 in order to prepare your report that are not listed and

1 identified in your report?

2 A My offhand answer is no.

3 Q Are there any documents that you -- and  
4 did you review every document that you received from the  
5 Miller Firm?

6 A Yes.

7 Q Are there any documents that you received  
8 from the Miller Firm that are not listed in your report?

9 A No.

10 Q The thumb drive that you have today that  
11 we're going to do something with, are there any  
12 documents that relate to your engagement in this  
13 litigation that are not on that thumb drive, stored  
14 somewhere else perhaps?

15 A Documents that relate to this -- I'm  
16 pausing answering the question because I would go to the  
17 FDA Web site and look at certain things to make sure I  
18 had the proper definitions.

19 I would look at some slides and presentations  
20 that I've done in lectures to make sure that I said the  
21 same thing or that I wasn't misleading any readers. But  
22 not counting that part my answer is I reviewed every  
23 document. There's nothing that I received that I didn't  
24 review.

25 Q Well -- and I guess I want to make sure.

1 Are there any documents perhaps -- you identified what  
2 you don't want to call drafts, but various versions of  
3 your analysis of various documents.

4 Are there any of those documents that you  
5 prepared, analytical type documents, that are not on  
6 that thumb drive?

7 A I'm thinking. My answer is no.

8 Q Okay. So every document that reflects  
9 your analysis of the materials you received as part of  
10 your engagement in this litigation, notes and everything  
11 is on that thumb drive?

12 A Every document?

13 Q Yes.

14 A I'm pausing again because I would go to  
15 the FDA Web site and look just to make sure certain  
16 definitions. I would look at some of my other work, the  
17 slides from lectures that I've given, to make sure that  
18 this is what I said and refresh my memory.

19 And they're on the C drive and not on here.  
20 But what I call official documents relevant to the case,  
21 my answer would be no. There's nothing -- maybe we  
22 ought to go back to the question again.

23 Q Yeah.

24 MR. ANDERTON: Can you read that back,  
25 please?

1 (The record was read back as requested.)

2 BY MR. ANDERTON:

3 Q And the key there, Mr. Farley, is  
4 documents that reflect your analysis or your work  
5 product.

6 A Documents. I'm -- then my answer is  
7 everything is on there.

8 Q Are there -- are your notes on there? Did  
9 you take notes? Let's start with that. Did you take  
10 any notes as you -- you know, you've described reviewing  
11 documents, preparing some sort of report on that review.

12 Did you first take notes before you prepared  
13 the review?

14 A I might during a review just jot something  
15 down, a word, a key phrase, and then I type the review.  
16 And I look down, word or key phrase, sometimes to make  
17 sure I got the word itself right and sometimes maybe  
18 just a spelling. And then I type it, it will look good,  
19 and at that time toss the notes out, because that's all  
20 they were for.

21 Q Okay. So you didn't keep any of those  
22 notes?

23 A I did not.

24 Q Do you -- did you mark up or write on any  
25 copies of the documents you received from the Miller



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1 Firm?

2 A Yes.

3 Q Did you bring those marked-up copies --  
4 well, did you keep those marked-up copies?

5 A Everything is in the case, the black  
6 suitcase and/or the tote.

7 Q Okay. So if you wrote up -- wrote on or  
8 marked up a document that you received from the Miller  
9 Firm and -- or as you reviewed it, that marked-up copy  
10 is with you here today?

11 A Yes.

12 Q Okay. Have you ever been involved in any  
13 consulting -- have you ever provided consulting services  
14 that related in any way to the manufacture of Digitek?

15 A No.

16 Q Ever been involved in any case that  
17 related to -- that related to Digitek in any way?

18 A No.

19 Q Did you review the Digoxin product label  
20 in this case, the Digitek product label?

21 A I'm not sure. I really just don't  
22 remember.

23 Q You don't remember because you don't  
24 remember that it was -- whether it was one of the 90 or  
25 so documents you received from the Miller Firm or just

1 don't remember?

2 A Once I knew that was a product that was  
3 either this case or part of it, I would look in the  
4 Physicians' Desk Reference to -- I will look at the  
5 molecule. I would want to learn more about it, what  
6 it's used for, various aspects of it. I would do that.

7 Q Other than the Physicians' Desk Reference  
8 what other medical literature did you review to prepare  
9 your report and the drafts -- or not -- I'm sorry -- not  
10 drafts but the different reports you prepared along the  
11 way?

12 A Can I look in the report?

13 Q You certainly may.

14 A Some of them I could tell you offhand, but  
15 for accuracy I think I better read the report.

16 Q Please. Mr. Miller will tell you I'm a  
17 slave to accuracy.

18 A That's what it's all about. Why be here  
19 if we're not going to be accurate?

20 Q I couldn't agree more.

21 A On page 16 and carrying over to page 17 --

22 Q And so that we're clear, Mr. Farley -- I  
23 apologize for interrupting you. But you're talking  
24 about pages 16 carrying over onto 17 of your report?

25 A Dated -- my report dated June 14th.

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1 Q Your final report?

2 A Yes.

3 Q Is that a fair characterization?

4 A Up to now it is my final report.

5 Q Okay. Well, you say up to now. Do you  
6 have any intention of revising it?

7 A Not on my account, not unless you say so.  
8 No, I don't have any intention to revise it.

9 THE VIDEOGRAPHER: Mr. Michael, I need to  
10 go off record and change tape, please, sir.

11 MR. ANDERTON: Okay.

12 THE VIDEOGRAPHER: We're off record at  
13 10:09.

14 (A brief recess was taken.)

15 THE VIDEOGRAPHER: It's 10:18 a.m. This  
16 is the beginning of Tape 2 in the deposition of  
17 James J. Farley.

18 BY MR. ANDERTON:

19 Q Welcome back, Mr. Farley. Thanks for  
20 coming back. You were I think when the tape ran out  
21 giving testimony about information on pages 16 and 17 of  
22 your final report. And I guess I just want to ask one  
23 final question or maybe two.

24 But the medical literature and other  
25 references identified in -- or on pages 16 and 17 of

1 your report, in your mind is that the total -- is that  
2 the complete list of resources other than documents you  
3 received from the Miller Firm that you reviewed in order  
4 to prepare your report?

5 A I'm thinking here. I'm relying on my  
6 knowledge, looking at perhaps some of my presentations,  
7 because I do instructional training that are not --  
8 these are books or what we would generally classify as  
9 documents.

10 So if I say yes for the documents, I would  
11 like to have as an exception from that any lecture  
12 materials I might have used, because I flip through them  
13 and look real quickly to check something, put it back  
14 and I just didn't write it down.

15 Q What -- well, then let's test your recall.  
16 What of your lecture materials do you recall reviewing  
17 as part of your work in this case?

18 A Among others, it's called CAPA, C-A-P-A,  
19 Corrective Action/Preventive Action. That's a program  
20 within the GMP, Good Manufacturing Practices structure.  
21 I looked at that.

22 I looked at forms that I designed for clients  
23 on how to handle deviations, forms I designed for  
24 clients on how to handle out of specification results.  
25 I looked at a lecture I gave on root cause analysis,

1 which is part of deviations and out of specifications  
2 results, all under the Corrective Action/Preventive  
3 Action umbrella within GMPs.

4 I would flip to them, just take a quick glance  
5 and didn't bother noting it on here. But -- and there's  
6 any number of things. That's just part of it.

7 Q Okay. And if we -- and I'm not saying  
8 that we definitely want to, but if we wanted to ask you  
9 to go back and identify and produce as many of those as  
10 you could definitively identify as something you  
11 reviewed as part of this case, you could do that?

12 A I could do it.

13 Q Okay. For at least some of them, I  
14 presume?

15 A Those that I remember --

16 Q Right.

17 A -- and those that you want, yes.

18 Q Okay. Going back a little bit, we talked  
19 about what you would do at the beginning of a typical  
20 engagement for a pharmaceutical company. And I believe  
21 you said that you'd want to gather some additional --  
22 not additional, gather some initial information and then  
23 prepare what you described as a proposal so that you and  
24 the prospective client are on the same page about the  
25 scope of the engagement.

1 Do you remember that testimony?

2 A Yes. Yes, I do.

3 Q Did you do that in this case?

4 A I wasn't called by Actavis to help  
5 Actavis.

6 Q I understand. You were contacted by  
7 Dr. Smart, who apparently had the front end or direct  
8 initial contact. But then you were contacted by  
9 Mr. Miller or somebody from his firm within a day or two  
10 after that, correct?

11 A Yes.

12 Q Did you talk to Mr. Miller or someone from  
13 his firm about the scope of your work or potential work  
14 in this litigation and did you prepare a proposal and  
15 submit it to him?

16 A I didn't prepare a proposal and submit it  
17 in this case that way, because my discussion with Peter  
18 Miller, as I was getting ready to ask the questions, he  
19 said, I have a binder of documents I will Fed Ex to you.  
20 To which I said, what does it have in it? Does it have  
21 483s, anything like that? And he said yes.

22 Fine, send me the documents, I will look at  
23 them and then determine what questions I have. Jumping  
24 for a moment, if I may, if I were going in to help a  
25 firm and defining the scope of work, I would say to the

1 firm, I want to know the results of your most recent  
2 internal audit and I want to know the results of the  
3 most recent two FDA inspections that you have. And that  
4 would give me a feel.

5 I didn't have to ask that in this case,  
6 because when Pete Miller and I talked on the phone and  
7 he said, I'll send you documents, I'll Fed Ex them,  
8 okay, I'll look at them and then see, the questions that  
9 I normally would have asked were answered by the  
10 documents that were contained in the binder.

11 Q Okay.

12 A Did I put it in the proper perspective?

13 Q Yes.

14 A Okay.

15 Q You've described four shipments containing  
16 perhaps five binders of documents --

17 A Yes.

18 Q -- all selected by Mr. Miller or somebody  
19 on -- associated with Plaintiffs' counsel, correct?

20 A Yes.

21 Q Did you ask for any specific documents  
22 other than those that you received from Mr. Miller in  
23 these binders?

24 A As we went along when I received the first  
25 binder -- let me start with the first binder, which had

1 25 tabbed sections. And it had Establishment Inspection  
2 Reports, 483s, various things on the list here in the  
3 report.

4 And I would start reviewing them and preparing  
5 the individual electronic files, the ones that are on  
6 the drive, on them. And then I would call Pete Miller  
7 and say, here's what I've got, do you have such and  
8 such, do you have this.

9 And the answer might be, we're in the process  
10 of getting them for you, keep working on what you've  
11 got, when we get them we'll send them to you. So there  
12 was dialogue intermittently all along.

13 Q Was any of that -- did you make any of  
14 those requests in writing?

15 A No.

16 Q E-mail?

17 A Maybe e-mail.

18 Q So you did have e-mail communication with  
19 Mr. Miller or with somebody from his firm starting  
20 during the period let's say December 2009 through today?  
21 You've have e-mail communications?

22 A Yes.

23 Q Do you have those e-mails?

24 A I did not print them out and bring them  
25 here. Much of it was scheduling or when to expect



1 another package. All my results I would confine to the  
2 reviews, the individual reviews, each of which is the  
3 electronic file, and to the report.

4 Q Are those e-mails on that thumb drive?

5 A No. I just didn't think to save them,  
6 because --

7 Q Well, I guess I want to make clear, you  
8 just -- a moment ago you -- the concept of saving them.  
9 Do you still have those e-mails?

10 A Not saved, per se. If someone went into  
11 my PC in the home office they would probably find them.  
12 But they're not where I could pull them up.

13 Q Okay. Are they -- I take it you have --  
14 what is your e-mail account?

15 A AOL.

16 Q Are they just in your AOL in-box  
17 somewhere?

18 A 30 days --

19 Q 30 days.

20 A -- and then --

21 Q So your belief is any e-mail that you  
22 would have received more than 30 days ago you no longer  
23 have?

24 A Correct. But can I add something to that?

25 Q If you like.

1           A    If it was an e-mail that I perceived had  
2   direct relevance to my evaluation of the data, I would  
3   have saved it and printed it out.  Much of them were I  
4   might get something from Nia saying, Pete's out of town,  
5   he'll get back to you in such and such or --

6           Q    From whom?

7           A    Nia, N-I-A, last name Barton, B-A-R-T-O-N.

8           Q    And who is that?

9           A    She is either a secretary or paralegal to  
10   Pete Miller.  And there was some scheduling.  I might  
11   send an e-mail, Pete, do you know when the deposition  
12   will be scheduled, simply for scheduling.  And since it  
13   was scheduling and in my mind they had no basis for my  
14   evaluation of this case, I didn't bother saving them.

15          Q    Okay.  When you asked for additional  
16   documents, did you ask for any Digitek batch records?

17          A    Yes.

18          Q    Did you get them?

19          A    I got one, the batch in question, I  
20   believe.

21          Q    Okay.  So let's make that clear.  As I  
22   read your -- the list of documents in your report, did  
23   you get a batch record or did you get records that  
24   relate to that batch?  And you understand the  
25   distinction?

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1                   A    I understand the distinction.  I got batch  
2 records.

3                   Q    You did?

4                   A    Yes.

5                   Q    Okay.  So you saw the actual production.  
6 Was that batch record contained within a larger  
7 investigation report?

8                   A    No.  That is one I got by e-mail.  And I  
9 downloaded it and I have it on my file.

10                  Q    Okay.  Do you happen to recall off the top  
11 of your head that that is Batch 70924?

12                  A    Since you've named it it rings a bell, and  
13 I believe that is it.

14                  Q    Okay.  And when you said the batch in  
15 question a moment ago, do you mean the batch where  
16 during manufacturing some tablets that were defectively  
17 thick were found?

18                  A    Is that 70924?

19                  Q    70924.

20                  A    Yes.

21                  Q    So the batch you asked for and received,  
22 one set of Digitek batch records, and that is the  
23 records that relate to the batch that had the -- what  
24 people have commonly referred to as the double thick  
25 tablets?

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1 A Yes.

2 Q Is that the only Digitek batch record you  
3 reviewed as part of your engagement in this litigation?

4 A Yes.

5 Q Is that the only Digitek batch record you  
6 received as part of your engagement in this litigation?

7 A Yes.

8 Q Mr. Farley, I've handed you a document  
9 that has been marked as Defendants' Exhibit 74.

10 Have you seen that document before?

11 A Yes.

12 Q That's a notice of the deposition here  
13 today?

14 A Yes.

15 Q And attached to it if you go all the way  
16 back -- it should be attached but is not. Oh, I'm  
17 sorry. It's in the -- on the first couple of pages.  
18 You see there's a list of documents that you are  
19 requested to produce?

20 A Yes.

21 Q Did you read that list before you came  
22 here today?

23 A Yes.

24 Q You're showing me a copy that has check  
25 marks on it and that is marked up.

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1           A    And I made little notes of what -- the  
2    proverbial thumb drive.

3           Q    Okay.

4           A    That's what --

5           Q    You know what?

6           A    You want it?

7           Q    I do.

8           A    You can see it.

9           Q    I do.

10           MR. ANDERTON: Can we mark this? And  
11    we're just going to mark it 74A, the follow-up  
12    practice of Mr. Moriarty. I don't like it but --

13           MR. MILLER: Wouldn't it be 74B? You  
14    wouldn't call it A. You'd call it 74B.

15           MR. ANDERTON: I said it's not my  
16    practice, so --

17           MS. DOWNIE: Well, we have 74, right?

18           MR. ANDERTON: Yeah, we have 74.

19           MS. DOWNIE: And then we would have --

20           MR. ANDERTON: But we don't have 74A.

21           MS. DOWNIE: And then 74A.

22    (Defendants' Exhibit No. 74A was marked.)

23           MR. MILLER: Not to mention we jumped  
24    from 45 to 74.

25           MR. ANDERTON: Well, Pete, I warned you

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1 about that.

2 MR. MILLER: Yes, you did but I still had  
3 to throw it in.

4 THE WITNESS: Was there anything attached  
5 to it? I handed you everything without looking at  
6 what might be behind it.

7 MR. ANDERTON: Let me take a look and we  
8 will only mark --

9 MR. MILLER: There's another copy of the  
10 report.

11 MR. ANDERTON: Is it the final copy?

12 THE WITNESS: June 14th?

13 MR. ANDERTON: Does it say June 14th?

14 MR. MILLER: The second page in the first  
15 paragraph.

16 THE WITNESS: If that says June 14th  
17 that's the extra copy I printed out for anyone who  
18 may need it.

19 MR. ANDERTON: Well, the copy that I  
20 have -- I thought it had the date right on the  
21 front. It does. Oh, this one does, too.

22 THE WITNESS: Left side, lower left.

23 MR. ANDERTON: So I'm going to give that  
24 back to you and we're going to mark only the  
25 notice that you took and -- or that you received

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1           and that you made comments on, or put some notes  
2           on.

3   BY MR. ANDERTON:

4           Q    So anyway, my question, Mr. Farley, my  
5   first question is -- and I'm looking at the -- what's  
6   been marked as 74A. And I'll give that back to you to  
7   hold for a moment.

8           Is it correct to say that you reviewed this  
9   notice carefully?

10          A    Yes.

11          Q    And that you checked your files to see  
12   whether you had any documents that were responsive or  
13   that were described by the categories on that notice?

14          A    Yes.

15          Q    Have you brought with you today all  
16   documents that are responsive to that notice?

17          A    To the best of my eyes those that were  
18   available. You see here I put not all e-mails are  
19   printed.

20          Q    Okay.

21          A    But in accordance with the way our  
22   discussion has been going I will give you a qualified  
23   yes.

24          Q    Okay. May I see that just for one second?

25          A    Yes.

1 Q I see some notes on here. Category No. 6  
2 asks you to produce all bills that the witness -- that  
3 you've rendered to attorneys and law firms.

4 Do you have those invoices with you?

5 A On the thumb drive. They're timesheets.  
6 I submit timesheets to Nigel and Denise Smart. I e-mail  
7 them. The week ends on a Saturday and I e-mail them  
8 usually on Monday morning. And that's the way we do it.  
9 I don't prepare a specific invoice in this case for  
10 Smart Consulting Group.

11 Q Okay. I see a comment next to -- well,  
12 let's stay with the invoices for a second. There's two  
13 sets of notes here, one that says 450 and one that says  
14 20,700. Can you tell me what those notes mean?

15 A Oh, sure. Those notes, it tells me --  
16 that should be 4,050.

17 Q 4,050?

18 A That's an error on my part. If I were  
19 inspecting me I would write that up because that's a  
20 wrong number.

21 Q That notice would be adulterated.

22 A I have received for 27 hours' work at  
23 150 -- that's right -- 4,050. I had at that moment 138  
24 hours outstanding, or 20,700 dollars owed to me by Smart  
25 Consulting Group.



1 Q And does that mean that the total work you  
2 had performed as of the time you did these -- had  
3 performed as of the time you did these calculations is  
4 the 20,700 plus what should be 4,050?

5 A As of the time I wrote them. And if you  
6 want to be up-to-date, add 19 hours for last week.

7 Q Okay. So 19 times 150, that's just shy of  
8 3,000 dollars, if my math is correct. Let's call it  
9 2,850.

10 A Yes.

11 Q Plus 4,050, plus 20,700?

12 A Yes.

13 Q Okay. I see a note on here that says with  
14 respect to No. 5, retainer agreements. You've got a  
15 verbal agreement with the Smart Consulting Group? Tell  
16 me that about.

17 A Well, I have a confidentiality agreement  
18 with them. But Nigel will just call me up and say, Jim,  
19 are you available for a project? What are you talking  
20 about, Nige? I mean, we've known each other for a dozen  
21 years now.

22 What are you talking about? Well, it involves  
23 this, it involves this, involves this. Okay, fine, it  
24 sounds like I've got the time for it, let's pursue it,  
25 who should I call or who should call me. That's the way

1 we work it, as I do with some other consulting firms,  
2 too.

3 Q When you said a moment ago it sounds like  
4 you've got the time for it, is that the only  
5 consideration you used to determine whether you're going  
6 to take an engagement like this one?

7 A No, it's not the only consideration. It  
8 would be the engagement itself. But if I didn't have  
9 the time for it, I couldn't handle it and it wouldn't be  
10 fair to tell them I could.

11 Q I'm looking at another document that was  
12 part of the stack of documents that you gave me. And  
13 before I mark this, it looks like it's a resume' but  
14 it's not labeled the same. And I can look at it and  
15 initially see that it might -- sorry for --

16 A That's okay. That's all right.

17 Q Is this the same thing as the CV that you  
18 attached to your report?

19 A That should be essentially the same thing.  
20 I may have in the report added my association with the  
21 Skidaway Institute of Oceanography here and with  
22 Memorial Health, The Cancer Research Institute.

23 I have affiliations with them, board member of  
24 one, safety -- and I believe -- and I'll be able to  
25 answer that in another second if I can just look down at

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1 this.

2 Q Okay.

3 MR. MILLER: Take your time.

4 A Yes. What I did -- this is my CV as I had  
5 it on my computer.

6 Q Okay.

7 A And since I just finished a three-year  
8 tenure on the board of the Skidaway Institute of  
9 Oceanography associated with the University of Georgia  
10 and since I am now on the institutional biosafety  
11 committee of Memorial Health, I figured I ought to put  
12 them on there. So this is what I work with. I added  
13 those two things to it and put it on the CV that's in  
14 the report.

15 Q The CV then that is attached to the report  
16 is essentially updated and current.

17 A Yes.

18 Q Is that correct?

19 A Yes. It's that plus those two things I  
20 mentioned.

21 Q And the date on the bottom of this is  
22 April of 2010. I'm going to go ahead and mark this.

23 MR. ANDERTON: Can you mark that 74B,  
24 please.

25 (Defendants' Exhibit No. 74B was marked.)

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1 MR. MILLER: Mike, may I see the report?

2 MR. ANDERTON: You may.

3 MR. MILLER: Thanks.

4 MR. ANDERTON: Take your time.

5 BY MR. ANDERTON:

6 Q So, Mr. Farley, I'm not going to spend any  
7 time on this. What's now been marked as 74B is your CV  
8 as it existed as of April 2010?

9 A Yes.

10 Q And you've since updated it?

11 A Yes.

12 Q When did you prepare the updated resume',  
13 or CV?

14 A As I was preparing the report I just  
15 thought, gee, there's something I should add, I've been  
16 associated with these two institutions, which are  
17 recognized as pretty good institutions down here, and I  
18 thought, well, I ought to put them on it. It was that  
19 simple of a deal.

20 Q Okay. I see in your CV a reference to --  
21 hold on one second. If you'll pick up Exhibit 44 with  
22 the difficult to read exhibit sticker. All right. On  
23 page 24 I see a reference to your taking a course in --  
24 or titled FDA Law and Evidence Development.

25 A Yes.

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1 Q Do you see that?

2 A Yes.

3 Q Tell me what that was.

4 A That was two weeks in Bandera, Texas, near  
5 San Antonio. And it's a course where certain people,  
6 generally if they're grooming you for more things, you  
7 go down and you take that course.

8 You're there in Bandera, Texas, for two weeks.  
9 You have your own cabin. You have your own homework  
10 assignments working with other students who are FDA  
11 personnel from other districts.

12 And the first week you're taught by FDA people  
13 and the second week every instructor is an attorney.  
14 All lawyers teach you.

15 Q Teach you what?

16 A They teach you the laws associated with  
17 evidence development or, as it says, law and evidence  
18 development courses. They're not trying to make you  
19 lawyers.

20 They're trying to say from their point of view  
21 if you have a sample that you're bringing in, here's the  
22 way it is, put the seal on it, make sure that the seal  
23 is signed.

24 They tell you how to handle the sample and  
25 other procedures, how to talk to people at firms, the

1 associated paperwork to make sure that the Department of  
2 Justice would then have a case that would be suitable  
3 for court.

4 Q So it's teaching FDA personnel how to  
5 conduct themselves in the field so that the legal staff  
6 can use what they collect and identify during an  
7 inspection?

8 A I would say just like you said, but I  
9 would not say the field. FDA personnel anywhere, any  
10 time, any situation to help the attorneys have a strong  
11 case.

12 Q Okay. You've written two books.

13 A I have two published. I have some more  
14 sitting. I have two published.

15 Q You've published two books.

16 A I have had published. They have been  
17 published by CRC Press. They're not self-published.

18 Q I understand. You've had two books  
19 published. Is that the best way to say it?

20 A Yes.

21 Q Okay. Do either of those books relate to  
22 the issues on which you gave your opinion in this  
23 litigation?

24 A No.

25 Q Mr. Farley, I have handed you a document

1 that is marked as Defendants' Exhibit 46.

2 A Yes.

3 Q Have you seen that document before? Take  
4 a moment or as long as you need to flip through it and  
5 determine whether you can -- or figure out whether you  
6 can answer my question as to whether you've seen it.

7 A I'm one of the authors.

8 Q Okay. So that means, yes, you've seen  
9 that before.

10 A Yes, I've seen it.

11 Q Tell me what it is.

12 A Gene Brooks, who owns Brooks Law on York  
13 Street in Savannah, and Jim Shipley, who at this writing  
14 had just passed the Bar exam and works for Gene, and I  
15 thought it would be good to join forces of a chemist who  
16 used to work at FDA, pharmaceutical and stuff, and  
17 attorneys.

18 I'm not familiar with Gene's cases, but I'd  
19 have to assume that some of them might involve this. So  
20 we co-authored this, he quoting the USC, me quoting the  
21 21 CFR.

22 We each quoted our own -- we brought our own  
23 areas of expertise into it. And it was published in  
24 Trial Magazine, which is the publication of the American  
25 Association of Justice, in November of '08.

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1 Q And you said a moment ago as you were  
2 giving that answer he offered his input on the USC, you  
3 on the CFR.

4 To be clear, that means -- by USC you mean  
5 United States Code?

6 A Yes, or in my words, he talked lawyer talk  
7 and I talked chemist talk.

8 Q Okay. So -- and the CFR -- and I need to  
9 be a little more methodical on how we break this down.  
10 The CFR you referred to, that's the Code of Federal  
11 Regulations?

12 A Yes.

13 Q So he offered his input on the law; you  
14 offered your input on regulatory issues?

15 A Yes.

16 Q You didn't -- you're not a lawyer?

17 A I'm not.

18 Q Okay. Do you know whether he represented  
19 the law correctly?

20 A Whether Gene represented the law  
21 correctly?

22 Q Yeah.

23 A I assume he did. I do not know if he  
24 represented the law correctly.

25 Q Okay. The Food, Drug and Cosmetic Act,



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1 that's -- if I say the Act will you understand that to  
2 mean that I'm talking about the Food, Drug and Cosmetic  
3 Act?

4 A Whenever our subject is general  
5 pharmaceuticals I would -- if I hear the Act I  
6 believe --

7 Q Okay.

8 A -- you mean the Food, Drug and Cosmetic.

9 Q Okay. I will try to be diligent and use  
10 the full name where I can, but if I get lazy and just  
11 say the Act, I hope you'll understand by that I mean the  
12 Federal Food, Drug and Cosmetic Act.

13 A The Act is fine.

14 Q Okay. The Act provides certain minimum  
15 standards. We've talked a little bit about GMP  
16 compliance and the area where you provide consulting.

17 GMP, which you have defined as Good  
18 Manufacturing Practices, the minimum standards for GMPs  
19 are set forth in the federal regulations, correct?

20 A Yes.

21 Q And that's the CFR that you referred to a  
22 moment ago?

23 A Title 21, 21 CFR.

24 Q The GMP regulations are very general,  
25 aren't they?

1 MR. MILLER: Object to form.

2 A I would say general. I don't know if I'd  
3 say very general. That's -- they're general.

4 Q Okay. So they don't provide specific  
5 details about how every act related to manufacturing,  
6 testing and otherwise producing a pharmaceutical product  
7 is supposed to be performed?

8 A They do not. May I say why they don't or  
9 would you rather me not yet?

10 Q Well, the reason they don't is because  
11 pharmaceutical companies are required to read and then  
12 interpret the regulations and develop their own  
13 procedures, correct?

14 MR. MILLER: Object to form.

15 A And then they submit them to FDA for  
16 approval. And once approved, they must adhere to what  
17 they themselves submitted and we like to say do the  
18 right thing the right way the same way every time.

19 That's why that the GMP say you have to do  
20 such and such. If you're a pharmaceutical firm you say,  
21 I'm going to do it this way, time, temperature,  
22 et cetera, and then you submit it. And the FDA approves  
23 it.

24 They approve it on the condition that you're  
25 going to do the same thing exactly that way every time

1 the way you said, we looked at and approved. And if you  
2 ever don't do it that way you're in violation.

3 Q Okay.

4 A So that was a lengthy dissertation, but I  
5 had to put it in proper perspective.

6 Q Well, and I just want to make sure because  
7 you didn't directly answer the question that I actually  
8 asked. You implicitly did, but I want to make sure that  
9 this record is clear.

10 The pharmaceutical companies take the general  
11 content of the GMP regulations and they develop their  
12 own procedures which provide the precise detail on how  
13 they're going to produce their products?

14 A And then submit it for approval.

15 Q Well, I need you to answer that question.  
16 Correct? They develop those procedures.

17 A Okay.

18 Q Is that a correct statement?

19 A I want to hear that one more time.

20 Q Is it a correct statement to say that the  
21 pharmaceutical company -- a pharmaceutical company that  
22 manufactures products in order to comply with the GMP  
23 requirements is required to read the regulations and  
24 then interpret those regulations and develop its own set  
25 of procedures that they believe comply with the

1 regulations?

2 A Yes.

3 Q And then as you said, they submit their  
4 interpretation, their procedures to the FDA for  
5 approval.

6 A Yes.

7 Q They're required to comply with their own  
8 procedures.

9 A Yes.

10 Q So when you talk about Good Manufacturing  
11 Practices, you're not just talking about the federal  
12 regulations.

13 A Correct.

14 Q You're talking about the regulations and  
15 also any internal procedures developed by a  
16 pharmaceutical company to interpret those regulations.

17 A Yes.

18 Q And interpretations are not uniform from  
19 one company to the next, are they?

20 A That's a tough one to answer yes or no.  
21 Can you reword that? If not, I'll just think a little  
22 more and try to give you an answer.

23 Q Well, if you want me to reword it I'll do  
24 my best. When a company reads the regulations and  
25 develops its procedures they're not just copying

1 something somebody -- another company has done, correct?

2 A Correct.

3 Q So every company's interpretation of a  
4 certain set of requirements can be different than --  
5 or the specific -- let me start this over.

6 The procedures a company develops to interpret  
7 and apply the regulations can be different than the  
8 procedures developed by another company to interpret and  
9 apply the exact same regulations.

10 A If I can explain what I think you mean --

11 Q Please.

12 A -- then I can answer the question.

13 Q Give it a shot.

14 A If one company, assuming there's two firms  
15 making the same product.

16 Q Right.

17 A One company selects a primary method of  
18 analysis for product release and uses what they call  
19 HPLC, high performance liquid chromatography, or a  
20 chromatographic method for the purity.

21 And that method says you will take such and  
22 such sample, you will prepare it this way, you will  
23 dilute it this way, you will run it in this solvent, you  
24 will do this and your answer must be no lower than this  
25 percent, no higher than this percent. Fine.

1           Now, if another company wants to make the same  
2   product but says, I think I'll do an ultraviolet  
3   spectrum method, they can develop their ultraviolet  
4   spectrum method, which is vastly different than  
5   chromatography, but they would have to say, I will take  
6   my sample and I will dissolve it this way, weigh it this  
7   way, I will scan it between this wavelength and that  
8   wavelength, I will do the following calculation. And it  
9   must be, for example, 98 to 102 percent done that way.

10           Each of those could be submitted and could be  
11   approved. But each of them has to stick with what they  
12   submitted.

13           Q    I agree with that.

14           A    So is that -- am I on track with answering  
15   your question?

16           Q    You absolutely are. So the short version  
17   of that is the two companies that you're describing can  
18   develop different methods for achieving the same  
19   compliance with the same regulation, develop -- or  
20   producing the same product?

21           A    Yes, provided they submit them, validated  
22   and stick with them once they're approved.

23           Q    Understood.

24           A    Yes, sir.

25           Q    And the standards that -- or I'm sorry.

1 The procedures that they develop, those can change over  
2 time?

3 A They --

4 Q They can change over time, correct?

5 A Not without approval.

6 Q But with approval they can change.

7 A With approval after the fact. There's a  
8 system of doing it.

9 Q Well, and let me make sure that we're  
10 talking about the same thing.

11 A Yes.

12 Q Are you talking about approval with  
13 respect only to analytical methods or are you talking  
14 about all practices and procedures a company utilizes to  
15 manufacture a product?

16 A Everything from raw materials received to  
17 finished goods going out.

18 Q Everything must be submitted and approved  
19 by the FDA before any changes are made?

20 A If you have a procedure that's been  
21 approved and you want to use another procedure -- it  
22 might be faster, more accurate, you think -- you have  
23 to --

24 Q Let me --

25 A Go ahead.

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1 Q I want to make sure that we're talking  
2 about the same thing. So I apologize.

3 A Okay.

4 Q But I get the sense that you're using  
5 procedure and when you use terms like faster and more  
6 accurate, you're using chemistry terms. You're still  
7 kind of limiting your answer to an analytical method  
8 type context.

9 A No, I'm not.

10 Q Okay.

11 A No.

12 Q If a company has a procedure for handling  
13 documents, who they go to, how they're routed, whether  
14 they're kept in secure storage, who has access to that,  
15 an SOP that speaks to those issues, is that something  
16 that has to be submitted to the FDA before it's changed?

17 A For handling documents?

18 Q Yes.

19 A Record storage?

20 Q It might not --

21 A We're not talking about stability  
22 testing --

23 Q No, no.

24 A -- storage, data that's important for  
25 safety?



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1 Q I'm just talking about --

2 A Record storage?

3 Q -- record storage, for example, batch  
4 records storage.

5 A You could --

6 Q Let's go through this. Batch record  
7 storage. When you produce a product you create a record  
8 reflecting that production process that's commonly  
9 referred to as batch record, correct?

10 A Yes.

11 Q And then documents that comprise a batch  
12 record vary from one company to the next.

13 A Yes.

14 Q The batch records are kept by companies as  
15 they manufacture products.

16 A Yes.

17 Q They're stored somewhere, I assume.

18 A Yes.

19 Q The methods for storing those batch  
20 records, who has access to them, how they're stored,  
21 whether they're stored electronically or in hard copy,  
22 whether they're kept in a locked room, not kept in a  
23 locked room, those methods are typically set forth in an  
24 SOP, correct?

25 A Yes.

1 Q And SOP means standard operating  
2 procedure.

3 A Correct.

4 Q You don't have to submit an SOP for that  
5 to the FDA before you modify it, do you?

6 A You do not.

7 Q Okay. So there are procedures that don't  
8 necessarily have to be submitted to the FDA that a  
9 company can change over time as it develops a better way  
10 to do things or just decides it wants to do something  
11 differently?

12 A The example you gave, correct.

13 Q There are other examples, right?

14 A There are probably others, uh-huh.

15 Q Probably a lot more.

16 A Yes.

17 Q Okay.

18 A Everything I was talking about was in  
19 direct manufacturing and testing line that would affect  
20 the quality of a product.

21 Q So you're talking about changing what  
22 people in the industry typically refer to as the method?

23 A Not just the test method. It could be a  
24 mixing procedure.

25 Q Okay.

1           A     If someone got a new mixer and said, I  
2     think I can mix for 30 minutes instead of 45, they would  
3     have to run batches simultaneously, tell the FDA and  
4     submit analytical data. They couldn't just say this is  
5     better, we think it's the same and use it. That would  
6     be a violation.

7           Q     And that starts all the way back at the  
8     submission of, if you're a generic manufacturer, the  
9     NDA -- the -- I'm sorry -- the ANDA --

10          A     The ANDA.

11          Q     -- the Abbreviated New Drug Application.

12          A     Yes.

13          Q     The specific methods, not just analytical  
14     methods, but the techniques that a company is going to  
15     use to manufacture that product, have to be set forth  
16     and then submitted to and approved by the FDA.

17          A     Yes.

18          Q     And so going forward from there, any  
19     changes to those techniques have to be submitted to and  
20     approved by the FDA.

21          A     Yes.

22          Q     But there are any number of SOPs that are  
23     relevant to a pharmaceutical company's operations that  
24     are mandated by Good Manufacturing Practices regulations  
25     that a company can change without submitting it to the

1 FDA.

2 A Yes. I would say in the case that you  
3 just gave, record storage as opposed to data  
4 acquisition, data acquisition where you're getting data  
5 relevant to the identity, strength, quality and purity  
6 of the compound, that has to be approved. But record  
7 storage, that would not have to be.

8 Q Okay. If a company doesn't comply with  
9 the procedures that are in place to manufacture a drug,  
10 does that mean that drug is adulterated?

11 A If the company doesn't comply with the  
12 procedures? I believe that's defined in the Act as the  
13 definition. If a drug is not manufactured in accordance  
14 with Good Manufacturing Practices it is considered  
15 adulterated. I believe the section is 501 or 502.

16 Q Okay.

17 A But, yes. My answer is yes.

18 Q Okay. So the definition of adulterated in  
19 the Act, the Food, Drug and Cosmetic Act, is focused on  
20 non-compliance with the procedures that are in place to  
21 manufacture that product.

22 MR. MILLER: Object to form.

23 A Yes. It's very broad, very broad. If you  
24 don't manufacture it according to GMPs it's adulterated.

25 Q Well, and I want to make sure that what

1 you just said is clear in the record. When you say if  
2 you don't manufacture it in accordance to GMPs, you mean  
3 if you don't comply with the GMPs while you're  
4 manufacturing it then it's adulterated.

5 A While you're manufacturing it.

6 Q Or if you don't comply with the GMPs  
7 either while you're manufacturing it or in some aspect  
8 of the production then the drug is adulterated.

9 A Yes.

10 Q Adulterated doesn't mean defective.

11 MR. MILLER: Object to form.

12 A Adulterated means it's not, to use FDA's  
13 terms, of the identity, strength, quality and purity  
14 that you purport -- they like that term -- purport to  
15 have and therefore, my words, you can't trust it to be  
16 of the quality it's supposed to be.

17 Q Well, adulterated actually doesn't mean  
18 it's not of the identity, strength, quality and purity.  
19 It means it wasn't manufactured according to the  
20 processes in place to try to make sure it meets the  
21 identity, quality, strength and purity. Isn't  
22 that right?

23 MR. MILLER: Object to form, misstates  
24 his previous testimony.

25 A Yes.

1 Q Okay. So adulterated doesn't actually  
2 mean the drug doesn't meet the identity, strength,  
3 quality and purity it is supposed to have, correct?

4 MR. MILLER: Objection, asked and  
5 answered.

6 A It means it can't be guaranteed to have  
7 that. So are we saying the same thing?

8 Q No, because I'm not sure that you're --  
9 you can have a drug that's adulterated and -- well,  
10 let's use an example.

11 If, if I have -- if I failed to comply with a  
12 procedure in the course of manufacturing a drug that  
13 relates to filling out a form or a part of the batch  
14 record, if I have an SOP that says the batch record is  
15 supposed to be filled out a certain way and I don't fill  
16 out the batch record correctly, is that a violation of  
17 GMPs?

18 A Technically, yes. Could I ask you to be  
19 more specific in that case? And I have a reason for  
20 asking that.

21 Q Well, what's your reason?

22 A My reason is I saw -- it's a good example  
23 of what we're discussing. I saw a case where the  
24 analyst put the initials and the reviewed by were the  
25 same initials. And you're not permitted to review your

1 own work. It has to be someone else.

2 So that's a violation. And technically that  
3 material was not produced in accordance with GMPs,  
4 because you had -- let's say a guy. It could be a guy  
5 or gal, those initials. A guy writes his initials there  
6 and then he reviews his own work. And that's against  
7 regulations.

8 Q Okay. So that --

9 A That's what I was thinking of when you --

10 Q And let's use that example. That product  
11 technically is adulterated.

12 A Because it was not produced in accordance  
13 with GMPs, yes.

14 Q It doesn't mean it is defective.

15 A It doesn't guarantee it's defective, but  
16 it leads you to question, you didn't make it the way you  
17 said you did, why didn't you make it right.

18 Q But the bottom line is that that product,  
19 the fact that it's adulterated for the reason you  
20 described does not mean the product is defective.

21 MR. MILLER: Object to form.

22 A If I interpret that is there a possibility  
23 that the product may still be good, then I agree with  
24 you.

25 Q Well, it's more than just a possibility,

1 right? I mean, in that case -- what I'm trying to  
2 establish, Mr. Farley, is you've got a circumstance that  
3 you described where if you apply a literal reading of  
4 the regulations that product is adulterated.

5 A Yeah.

6 Q To determine whether the product is  
7 defective you'd have to actually test the product,  
8 right?

9 A Yes.

10 Q So to determine whether the product is --  
11 was actually manufactured within the specifications for  
12 the product, you'd have to test it.

13 A To determine if it was actually  
14 manufactured within the --

15 Q Yes, whether it actually has --

16 A Whether it is what it's supposed to be?

17 Q Yes. You have to test it.

18 A Yes.

19 Q So the fact that it's adulterated doesn't  
20 tell you whether it's within specification.

21 A It does not tell me it's within  
22 specifications, but I -- if a firm said to me, look at  
23 this contract manufacturer, and I went to the contract  
24 manufacturer that my client firm wanted me to give an  
25 opinion on and I saw that, why are you doing this? Why?



1 I mean, how do I know to trust you with anything else  
2 you're doing? You're fouling up here. And my  
3 recommendation would be to the pharmaceutical firm,  
4 don't deal with them, because --

5 Q You've really --

6 A -- it leads you to wonder.

7 Q Because one -- non-conformance with one  
8 practice or procedure you'd recommend not dealing with  
9 them at all?

10 A I recommend not dealing with them until  
11 they found out why and what the reason was for it and I  
12 would -- I've done it. I've said to a firm, I would  
13 seriously consider not dealing with Contract  
14 Manufacturer A and here's the reason, it's in my report.

15 Q Well, and don't -- let's take it out of  
16 the context of a company potentially dealing with a  
17 contract manufacturer.

18 A Okay.

19 Q Let's just deal with a company that's  
20 manufacturing products.

21 A Everything in-house.

22 Q Right. So if a product is adulterated --  
23 we've already established that doesn't mean it's  
24 defective -- it doesn't say anything about whether it's  
25 safe or unsafe either, does it?

1 MR. MILLER: Object to form.

2 A It doesn't say definitely that's it's safe  
3 or unsafe.

4 Q It doesn't say anything about whether it's  
5 safe. You'd have to test the product to make that  
6 determination.

7 A Yes.

8 Q I'd like to talk a little bit about some  
9 of the things in your article. If you'd pick up  
10 Exhibit 46, please.

11 A I have it.

12 Q Give me one second. This is what happens  
13 when you leave your highlighted copies. You said a  
14 moment ago that the procedures a company is going to use  
15 to develop its -- or to produce its drugs are submitted  
16 to and approved by the FDA; is that correct?

17 A Yes.

18 MR. ANDERTON: Let's take a couple of  
19 minute break. We're about -- we're about there,  
20 aren't we?

21 THE VIDEOGRAPHER: Yes, sir.

22 MR. ANDERTON: Okay. Let's take a couple  
23 of minutes and then I can get a little more  
24 organized on this.

25 THE VIDEOGRAPHER: We're off the record

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1 at 11:11.

2 (A brief recess was taken.)

3 THE VIDEOGRAPHER: It's 11:20 a.m. We're  
4 back on record and this is the beginning of Tape  
5 No. 3 in the deposition of James J. Farley.

6 BY MR. ANDERTON:

7 Q Mr. Farley, if you will pick up the  
8 article, your -- the article that you co-authored and  
9 look at the first page. It's -- and I'm talking about  
10 Exhibit 46.

11 You see the bottom, the very bottom of page 1  
12 and continuing on to page 2, the last sentence of that  
13 last paragraph on page 1 reads, The FDA's acceptance of  
14 submitted procedures is evidence, not conclusive proof,  
15 of the reasonableness of the company's manufacturing  
16 practices and procedures, and the trier of fact may  
17 assign FDA approval the weight it deserves.

18 Did I read that correctly?

19 A Yes, you did.

20 Q Do you agree with that statement?

21 A I'm going to read it one more time.

22 Q Take your time.

23 A Of course, I've known Gene since we moved  
24 down here five years ago and I would be reluctant. But  
25 I'm going to do just like you said.

1 Q Well, let me ask you first, is that  
2 something you drafted or Mr. --

3 A Gene Brooks.

4 Q -- Brooks drafted?

5 MR. MILLER: Give him a chance to read  
6 it.

7 MR. ANDERTON: I am. I am.

8 Q Take your time. Why don't you go ahead  
9 and review it as you need to.

10 A When you get into terms like trier of  
11 fact, that's Gene. And -- but he -- sometimes we just  
12 meet for lunch. Other times he'd send me an e-mail.  
13 And we look and he says, this is my statement, and I  
14 say, well, yeah. The FDA's minimum standards you have  
15 to at least do this. That's the way I would have wrote  
16 that.

17 Q Okay. So it's minimum standards?

18 A Yes.

19 Q If you comply with the submitted  
20 procedures, as the term used here, you submit procedures  
21 and get them approved by the FDA. If you comply with  
22 those, have you achieved compliance with Good  
23 Manufacturing Practices?

24 A If you comply with every procedure -- and  
25 I'm going to use my terminology again of raw materials

1 received to finished product. If you comply with all of  
2 them there are cases where companies comply in one area  
3 and they in fact foul up or are violative in another.  
4 That ruins the whole -- right on down the line  
5 everything has to be in compliance. Then, yes.

6 Q Well -- okay. But I guess I want to make  
7 sure that you answered my question, Mr. Farley.

8 A Okay.

9 Q If you comply with the submitted  
10 procedures, have you achieved GMP compliance?

11 MR. MILLER: Objection, asked and  
12 answered. It's okay to answer.

13 A If you comply with every one of the  
14 submitted procedures that had been approved relevant to  
15 the manufacturer of a given product then --

16 Q Have you achieved GMP compliance?

17 A Yes.

18 Q And you believe that a jury could still  
19 hold the manufacturer liable and award damages if  
20 somebody achieved that compliance that you've just  
21 described?

22 MR. MILLER: Objection, misstates facts  
23 in evidence and previous testimony.

24 A I don't know what goes on in jury's minds.  
25 I don't know how I can answer that.

1 Q Okay. So you can't -- I guess that means  
2 you really can't speak to whether that sentence that I  
3 read regarding whether a trier of fact -- or regarding a  
4 trier of fact assigning its own weight, you can't agree  
5 or disagree with that?

6 MR. MILLER: Object to form.

7 A Well, I will agree with anything that I  
8 wrote here. But your question was what I thought would  
9 go on in a jury's mind and I have no idea what goes on  
10 in a jury's mind.

11 Q But you -- so then you agree with what's  
12 written here?

13 A I wrote it. I have to. Definitely.

14 Q Okay. So you think a jury can take a  
15 company that's achieved GMP compliance and still hold it  
16 liable?

17 MR. MILLER: Object to form, misstates  
18 the testimony.

19 A I'm not getting the connection of -- it  
20 sounds like you're changing subjects on me.

21 Q No. I'm talking about this sentence. If  
22 you agree with it then you think that a jury can take a  
23 company that is complying with Good Manufacturing  
24 Practices and say, not good enough, we're going to hold  
25 you liable.

1 MR. MILLER: Object to form. That's not  
2 what it says.

3 A I'm not deliberately trying to be evasive.  
4 I just -- I'm not getting it. I'm not --

5 Q Do you agree with what I just asked?

6 MR. MILLER: Object to form.

7 A I'm still going to ask you one more time.

8 MR. ANDERTON: Can you read that back,  
9 please?

10 (The record was read back as requested.)

11 MR. MILLER: Mike, that's not what the  
12 statement says.

13 A If the company complied with Good  
14 Manufacturing Practices on every approved -- FDA  
15 approved procedure from raw materials in to finished  
16 product out --

17 Q Yeah.

18 A -- and didn't turn the other way for any  
19 other situation, like if a carton was broken putting on  
20 a truck and they look the other way and said, forget it,  
21 we're done, if they did that then they've done  
22 everything in accordance with FDA regulations.

23 Q Can a jury hold them liable for damages in  
24 that context if a consumer takes their product and is  
25 injured?

1 MR. MILLER: Object to form.

2 A I can't predict what a jury would do.

3 That's what I'm having trouble with.

4 Q I'm not asking you to predict what they  
5 will do. Are they permitted to do that?

6 MR. MILLER: Object to form.

7 A A jury is permitted to do whatever the  
8 judge tells them within the range.

9 Q And you think it's appropriate that a  
10 company that achieves that absolute compliance that you  
11 just described can be held accountable -- or can be held  
12 liable for damages?

13 MR. MILLER: Object to form. Mike,  
14 you're misstating -- you're asking questions about  
15 a statement that don't compare.

16 Q Okay. I'm asking a question that I think  
17 flows directly from this sentence, so --

18 A I'm pausing because I haven't seen a  
19 company that has been in complete compliance ever get in  
20 a situation like that. When you're in compliance you  
21 don't get involved in that thing.

22 Q So if you're in compliance you never get  
23 sued?

24 A I can't say never get sued. I say that in  
25 my eyes if you're in compliance you are quite likely



1 making a quality product.

2 Q That doesn't mean you can't get sued.

3 MR. MILLER: Object to form.

4 A No. You can get sued any time for  
5 anything. Whether it goes through or who decides what,  
6 that's another story.

7 Q If a consulting -- a prospective  
8 consulting client -- well, let's not call it  
9 prospective.

10 If you are hired by a pharmaceutical company  
11 to consult as to how to avoid litigation -- have you  
12 ever been hired to do that?

13 A Specifically help me to avoid litigation?

14 Q Yes.

15 A No, not in those words, no.

16 Q Okay. If a company hired you as a  
17 consultant to advise it how to achieve regulatory  
18 compliance -- well, if a company -- let's -- I'm going  
19 to not ask that question. I'm going to start a brand  
20 new question. Okay?

21 If a company hired you and said, Mr. Farley,  
22 we'd like you to tell us how to manufacture and produce  
23 any product, it doesn't matter what the product is, and  
24 we want to do it so that we minimize or eliminate the  
25 possibility of getting sued by consumers, what would you

1 tell them?

2 MR. MILLER: Object to form of the  
3 question.

4 Q What would your approach to that  
5 engagement be?

6 A Word for word the way you just presented  
7 it, I'd say, well, as far as getting sued, I don't have  
8 anything to do with that. Anybody can sue you any time.  
9 You want to get in compliance, I'll talk to you about  
10 getting in compliance.

11 As far as litigation, you talk to your  
12 attorneys about that. I will help you get in compliance  
13 and then I would go through the procedures as how -- I  
14 would be asking them records of their previous  
15 inspections, their previous internal audits.

16 But I wouldn't answer it the way it was  
17 phrased, because I can't tell whether you're going to  
18 get sued or not. I will say, I can give you -- I will  
19 make you be in compliance -- I will help you be in  
20 compliance, I'll show you how to do it. And it would --  
21 that would be it.

22 Q And would you do that because if they were  
23 in compliance they, as you said a few moments ago, they  
24 don't find -- they wouldn't find themselves in that  
25 situation or they'd be less likely to find themselves in

1 that situation?

2 A I would relate the more you are in  
3 compliance the less possibility of litigation coming  
4 about or a lawsuit being filed against you. I would  
5 believe there's a relationship there.

6 Q Okay. Go to page 3 of this article,  
7 please.

8 A Okay. I'm on 3.

9 Q And I want to -- first I want to ask you  
10 about the headings. You've got -- on the first  
11 heading -- actually there are no headings until you get  
12 to page 3. But then you start having headings,  
13 Prefiling Investigations, Discovery, Standard Operating  
14 Procedures, Documentation of Internal Plant  
15 Construction, FDA Inspection Documents.

16 Do you see those headings?

17 A Yes.

18 Q You know, the title of this article,  
19 Mr. Farley, is "Discovering the Cause of a Drug's  
20 Defect". It reads more to me like a how to manual on  
21 how to sue pharmaceutical companies.

22 Am I mischaracterizing it by reading it like  
23 that?

24 MR. MILLER: Object to form.

25 A I think that a person could interpret it

1 like that, but that was not my intent. Gene and I  
2 thought, let's put our heads together and let's write an  
3 article. Gene never expressed to me that it was his  
4 direct intent.

5 We just thought it would be nice to work  
6 together on an article and get it out into the industry.  
7 And I thought it would be nice to work on something that  
8 would appear in a law journal.

9 Q Didn't care what the subject was or what  
10 impression it might have?

11 MR. MILLER: Object to form.

12 A Didn't care. That's a question mark,  
13 didn't care. There are certain ones I probably wouldn't  
14 write, either not knowledgeable or just didn't care to  
15 talk about. But since it sounded like a good subject,  
16 product liability, and we both had an interest in it, we  
17 put our minds together and wrote it.

18 But it was not my intention and I believe,  
19 knowing Gene and Jim the way I do, that -- and I'm  
20 guessing here -- that it's not their intention to how to  
21 sue manual.

22 Q Well, knowing what you do, what -- do they  
23 handle cases where consumers sue pharmaceutical  
24 companies?

25 A I don't know anything about Gene's cases.

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1 Q Nothing?

2 A Nothing.

3 Q You don't know anything about his cases?

4 A I've never done work for Gene. He's  
5 referred me to other attorneys, one in particular in  
6 town for whom I did some work. But I have not worked  
7 for him directly.

8 It's more of a -- I don't know if I should use  
9 the word social, but just -- he was someone I met when  
10 we first moved to Savannah and he clued me in on  
11 different things in Savannah and we hit it off more as  
12 friends.

13 Q Okay. Turn to page 3 of your article,  
14 please.

15 A I'm there.

16 Q Do you see the paragraph under the  
17 Prefiling Investigation heading, the third paragraph on  
18 page 3?

19 A It starts with the word Microbiological?

20 Q No. Do I have a different copy than you?

21 A I'll show you mine. That's what I've got.

22 Q Third paragraph. I'm sorry. Not -- the  
23 third paragraph on the page. I didn't say that clearly.  
24 My apologies.

25 A It begins with, When a client?

1 Q That's the one.

2 A I'm there.

3 Q It reads, When a client comes to you  
4 suspecting that he or she has taken an adulterated drug,  
5 you should tell the client to save the drug, the  
6 container and all labeling and packaging information. A  
7 laboratory must analyze the drug and test for its active  
8 pharmaceutical ingredient, paren, API, closed paren, and  
9 for strength and purity.

10 Did I read those two sentences correctly?

11 A Yes, you did.

12 Q So if you think a drug is adulterated you  
13 have to test it to determine whether it was defective.  
14 We established that earlier, right?

15 A Yes.

16 MR. MILLER: Object to form, misstates  
17 previous testimony.

18 Q Well, that's what this says, right?

19 A Well, what -- to put that in perspective,  
20 I remember we were talking about it and Gene said to me,  
21 what's the first thing you do? I said, if someone took  
22 a drug and had some sort of adverse event, adverse  
23 effect, and they thought something was wrong with it, if  
24 you are going to represent them or anyone who wants to  
25 learn more about the situation, either side, so to

1 speak, your best bet is that container, the remainder of  
2 the material in it, and get data right there as opposed  
3 to comparing it to something that was made at some other  
4 time.

5 Q Okay.

6 A So that's what we were talking about here.  
7 Your best bet is do you have the same container of  
8 medication and what's the lot number. And you can be  
9 more specific in getting to the solution of the problem.

10 Q And ultimately what you're describing is a  
11 method to determine whether the product was defective.

12 A Yes, for either side.

13 Q Understood. And you should make that  
14 determination whether the product is defective before  
15 you file a lawsuit, shouldn't you?

16 MR. MILLER: Object to form of the  
17 question.

18 A That's for an attorney to judge, but I  
19 would think so. But I don't feel that -- I feel  
20 attorneys are better qualified for that because they  
21 represent their clients.

22 Q Okay. Can you sue a pharmaceutical  
23 company just because you take a product that's  
24 adulterated?

25 MR. MILLER: Object to form of the

1 question.

2 A You being an individual?

3 Q A consumer, yes.

4 A Can you sue a pharmaceutical company just  
5 because you took a product that's adulterated? That's  
6 between you and your attorney.

7 Q You don't know?

8 A Well, I know that anybody can sue anybody  
9 over anything any time in the U.S. today.

10 Q Well, you also know --

11 A So that would be yes.

12 Q Well, but is adulterated -- well --

13 A I think, if I can interject something --

14 MR. MILLER: Hold off. There's no  
15 question. When he asks a question you can answer.

16 Q Yeah, Mr. Farley, I appreciate that and  
17 I --

18 A I'm holding off.

19 Q Okay. Look at the heading on -- still on  
20 page 3 that says Discovery. Do you see that heading?

21 A Yes.

22 Q It's important to request and review  
23 documents when you're considering whether you should --  
24 whether you can and should sue -- well, take that back.  
25 It's important to request and review documents



1 if you're trying to figure out whether you've got a  
2 claim against a pharmaceutical company, correct?

3 A Yes.

4 Q And that includes reviewing batch records.

5 A Reviewing --

6 Q Batch records.

7 A Batch records, yes.

8 Q I mean, you say in the article here that  
9 you should start by requesting a review of the batch  
10 records; is that right?

11 A Of that particular lot of the bottle in  
12 question, or container in question.

13 Q If you can do that you should -- that  
14 should be the first place you look is you look at batch  
15 records of that particular lot.

16 A Yes.

17 Q And that will tell you whether the product  
18 was manufactured in compliance with Good Manufacturing  
19 Practices.

20 MR. MILLER: Object to form of the  
21 question.

22 A Yes. It's the first place to look. Deal  
23 with the specific product that seems to be causing their  
24 problem.

25 Q I understand. And like I said, that will

1 tell you whether the product was manufactured in  
2 compliance with Good Manufacturing Practices.

3 MR. MILLER: Object to form of the  
4 question.

5 A If everything on it is presented  
6 accurately and honestly, yes.

7 Q Okay. Your expert opinion in this case  
8 doesn't speak to the accuracy of Actavis' documents,  
9 correct?

10 A Doesn't speak to the accuracy of Actavis'  
11 documents?

12 Q Yeah. You don't offer an opinion about  
13 whether the documents -- whether Actavis' records are  
14 accurate.

15 MR. MILLER: Object to form of the  
16 question.

17 A Specifically -- I noticed something in  
18 that double initial where the analyst was also the  
19 reviewer, which I noticed that. I also in another  
20 document that I could find upon a short search where I  
21 saw an analysis of an impurity.

22 And those results jumped out at me like they  
23 are so precise, I mean, abnormally precise, more precise  
24 than most people would see, which leads you to wonder  
25 did they really run it. But that's speculation, of

1 course. But that would -- so if everything was correct  
2 then the product should be good. But --

3 Q But I want to make --

4 A What was your original question?

5 Q My question is, you're not offering an  
6 opinion in this case about whether Actavis' documents  
7 are accurate, are you?

8 A I have questions about some of the things  
9 on them, but the way you worded the question, I am not  
10 questioning. I'm not believing they all are accurate,  
11 but I'm not questioning them.

12 Q There's nothing in your report expressing  
13 any opinion that the information in Actavis' documents  
14 is inaccurate, right?

15 MR. MILLER: Object to the form of the  
16 question.

17 A There is an opinion in one file where they  
18 did an impurity determination and they got -- I believe  
19 it was 1.61 percent and 1.61 percent. And I said these  
20 are fantastically precise results.

21 And I questioned the accuracy, one might even  
22 say the legitimacy of that. I would like to see the  
23 analyst's records on that. I don't have them. I would  
24 like to see them.

25 Q When you say in one file, you're not

1 talking about your report?

2 A In one of the documents I reviewed, one of  
3 the 93 documents.

4 Q So if I understand correctly, in one of  
5 the 93 documents you reviewed you saw one test result  
6 for impurity that in your mind caused you to question  
7 some aspect of the performance of that test.

8 A No, no. In one I saw a set of results  
9 that led me to question that. There were a series of  
10 analysis. It wasn't just one. One would not cause me  
11 to question it, but a series did. And in another I saw  
12 the analyst and reviewer having the same initials.

13 Q There's no mention of either of those  
14 things in your expert report.

15 A Not in the report. It's in the files I  
16 reviewed, the individual files.

17 Q I understand. So you're talking about  
18 information in documents that you reviewed --

19 A Yes.

20 Q -- not in your expert report which  
21 contains your expert opinions, right?

22 A Yes.

23 Q You understand --

24 A Yes, you're correct it's not mentioned in  
25 the report specifically.

1 Q And you understand, Mr. Farley, that  
2 you've been retained as an expert witness in this  
3 litigation to give an expert opinion on certain  
4 subjects.

5 A Yes.

6 Q The accuracy of Actavis' documents is not  
7 one of those subjects; is that correct?

8 A It is not one of them. Some things raise  
9 eyebrows, but I did not have enough data to make a  
10 conclusive decision. Did that answer it? I know it  
11 might be answered, but I'm trying to put it in the  
12 proper perspective for you, for all of us.

13 Q It's your answer. The FDA when it  
14 conducts inspections and based on your experience, if  
15 they thought a company had fraudulent or falsified  
16 documents, they'd take very swift and very decisive  
17 action, wouldn't they?

18 A I would hope so. And I've known them to  
19 do it in those cases.

20 Q Okay. And what actions would they take?

21 A They immediately do a review of all  
22 relevant documents to look for the extent of it and the  
23 backgrounds of the individuals involved.

24 Q What action would they take with respect  
25 to that company's continued participation in the market,

1 leaving their products in the market?

2 A Until they were sure they would be doing  
3 the investigation. It's like any time. You're doing  
4 the investigation but you -- it depends on the potential  
5 result out here as to whether you shut them down now or  
6 have a potential for shutting them down later. They  
7 would do the investigation, depending on where they  
8 thought the fraud was.

9 Q You reviewed a series of FDA documents --

10 A Yes.

11 Q -- relating to Actavis, correct?

12 A Correct.

13 Q No reference to even the possibility of  
14 fraud in any of those documents, is there?

15 A Correct.

16 Q So the FDA didn't think Actavis' documents  
17 were fraudulent.

18 A Correct.

19 Q When you're -- let's go back to documents.  
20 If you're looking at -- I'm sorry. Let's go back to  
21 your article and specifically your review of batch  
22 records.

23 If you're looking to -- and if you look at  
24 the -- your discussion of batch records here, it goes on  
25 for almost a page. And if you look at the second

1 paragraph on page 4 it starts -- well, no, the first  
2 full paragraph, Batch records contain a wealth of  
3 information about the production history of a specific  
4 drug.

5           These records contain the names of people  
6 actively involved in the manufacturing process,  
7 operating procedures followed -- and there's a  
8 parenthetical -- relevant dates and times and, most  
9 important, the results of sample tests.

10           Essentially what you're saying in this article  
11 is you're looking for evidence of GMP violations.

12           A    I'm looking to see how it was  
13 manufactured. If I was looking for a violation that's  
14 where I would look for a violation. If I was looking to  
15 see that they made it correctly that's where I would  
16 look to see that they made it correctly.

17           I guess my answer is it depends what side  
18 you're on and what you're predisposed for looking. But  
19 that's going to give you the answer.

20           Q    Objectively if you're looking for those  
21 through batch records -- and I guess if you're on the  
22 plaintiff's side you're looking for evidence of GMP  
23 violations when you review the batch records.

24           A    Yes. Of course, the firm itself does --  
25 should do periodic reviews to ensure that everything is

1 correct. That's why I'm saying both sides. When firms  
2 do their own audits, which they should do periodically,  
3 they would review batch records, not looking expecting  
4 something is wrong, but expecting everything to be  
5 correct.

6 Now, a plaintiff's representative, on the  
7 other hand, might review it looking for that. So that's  
8 why I'm saying, you can review it either way depending  
9 on what you're looking for.

10 Q You're looking for different things, but  
11 neither side can determine -- let's ask a slightly  
12 different question.

13 You can't determine if there were GMP  
14 violations associated with manufacturing a product  
15 without reviewing the batch records, correct?

16 A There are cases where you could. There  
17 are cases where it would be obvious. You look at the  
18 product and you see a crack or a double size. I mean,  
19 double size, I don't need to look at a batch record  
20 to -- I want to look at the batch record after the fact,  
21 but I can see there's something wrong here.

22 Q Assuming you're not holding product that  
23 is obviously -- well, let's explore that concept. Let's  
24 assume you're looking at a double thick tablet. It  
25 doesn't mean it was -- GMPs were violated when it was



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1 manufactured, does it?

2 A If you're looking at a product, just the  
3 product, that's it.

4 Q Yeah.

5 A You have the product in your hand.

6 Q Yeah. It's twice the size it should be.  
7 That could happen even if you have absolute strict  
8 compliance with all relevant Good Manufacturing  
9 Practices in the production of that product, correct?

10 A Provided it didn't get to the consumer.  
11 You're talking about the employees.

12 Q If it gets to the consumer that doesn't  
13 change whether it was manufactured properly.

14 A What does matter is what did you do about  
15 it. Did you --

16 Q Mr. Farley --

17 A -- do an investigation --

18 MR. MILLER: Let him answer the question.

19 Q -- answer my question. If I have a  
20 defective tablet in my hands --

21 A Defective, your word.

22 Q Okay. It's twice as thick as it should  
23 be.

24 A Yes.

25 Q It doesn't mean any GMPs were violated in

1 manufacturing that product, does it?

2 MR. MILLER: And continue with your  
3 answer when you were cut off, please.

4 A It means something is wrong somewhere.  
5 This is not the product we want. Let's launch a  
6 Corrective Action/Preventive Action investigation into  
7 it. And then that would have to be launched the proper  
8 way to investigate it.

9 It means something went wrong somewhere. And  
10 at that point you don't know where or why, but you have  
11 to investigate it. Failure to investigate it would be a  
12 GMP infraction.

13 Q Okay. But you still haven't answered my  
14 question.

15 A Okay.

16 Q It doesn't mean --

17 A One more time.

18 Q -- anything -- any GMP was violated while  
19 it was being manufactured.

20 A Yes, it does.

21 Q What --

22 A Because it's supposed to be a certain  
23 weight and a certain size.

24 Q Okay. But --

25 A And it's not.

1           Q    How could you know what GMP was violated  
2   just because it's out of specification?  You can -- is  
3   it true or not you can comply with every single GMP  
4   requirement associated with manufacturing a product and  
5   still produce a product that happens to be out of  
6   specification?

7           A    Theoretically you're not complying.  
8   Something went wrong somewhere.

9           Q    Something went wrong doesn't mean you  
10  didn't comply with Good Manufacturing Practices.

11          A    The system that you're trusting didn't  
12  comply --

13          Q    That doesn't mean --

14          A    -- that you --

15          Q    That means something went wrong.  That  
16  doesn't mean you didn't comply with Good Manufacturing  
17  Practices, does it?

18          A    You try to comply.  You didn't make a  
19  double thick tablet deliberately.  But once you saw it  
20  was double thick you know here's the specifications for  
21  thickness and for weight, this is too thick and it  
22  weighs too much, something is wrong with the system,  
23  let's investigate it.

24                It's a defective product as you yourself said.  
25  And what are we going to do about it?  What are you

1 going to do about it now? That's --

2 Q You're talking -- but now you're talking  
3 about after the fact. And I agree. If you have a  
4 defective product and you learn of it, perhaps from a  
5 consumer, perhaps it comes back from a pharmacist, I  
6 agree that now you have to determine what you're going  
7 to do about it.

8 But you're not answering my questions about  
9 the processes that resulted in production of that  
10 product. You can comply -- is it true or not, you can  
11 comply with every single Good Manufacturing Practice  
12 associated with manufacturing a product and it is still  
13 possible that you could produce a product that is not  
14 within specifications?

15 MR. MILLER: Objection, asked and  
16 answered.

17 A Here's -- I'm going to reword a certain  
18 way, because I can't answer that yes or no. I'm going  
19 to say you can believe you complied with everything  
20 according to the way your high moral character, your  
21 high ethics and the way you set your system up.

22 But you've got the evidence sitting right  
23 there in the palm of your hand something is wrong  
24 somewhere. I obviously didn't comply. Why didn't I and  
25 how can I fix it?

1 Q You -- it's not that you didn't comply.  
2 It's that you -- the process didn't work properly. That  
3 doesn't mean you didn't comply, does it?

4 A The process didn't produce the material  
5 within specifications; therefore you didn't comply.

6 Q That's not true.

7 A You didn't mean not to comply, but you  
8 didn't comply.

9 Q You didn't produce a product that was  
10 within your specifications. That does not -- do you  
11 believe that automatically means you didn't comply with  
12 the procedures you were supposed to?

13 A Yes, I do. And what comes to mind is did  
14 Prius comply with the accelerator pedal? Is BP  
15 complying with the oil in the Gulf? I mean, you know,  
16 something is wrong somewhere, because the cars are going  
17 there, your oil is going out in the Gulf.

18 You've got a tablet in your hand that you  
19 acknowledge is defective. You didn't mean not to  
20 comply, but you didn't comply, because if you did you  
21 would have had a quality product that met  
22 specifications. You wouldn't have that double thick  
23 tablet in your hand.

24 Q The Good Manufacturing Practices  
25 regulations require that you develop a procedure for

1 every step in the process of manufacturing a product,  
2 correct?

3 A Yes.

4 Q And they require that you submit those to  
5 the FDA --

6 A Yes.

7 Q -- and get approval, right?

8 A Yes.

9 Q And then they require that you follow  
10 those procedures, right?

11 A Yes.

12 Q If you do that, develop them, submit them,  
13 follow them, have you achieved compliance with Good  
14 Manufacturing Practices?

15 A If you look at your final product and it  
16 meets all the specifications assigned to that product  
17 and approved by the FDA, then you have. If it does not  
18 meet those specification then you have, by your  
19 definition, a defective product and you didn't comply  
20 even though you thought you did and you meant to.

21 Q How does that speak to whether you  
22 complied? Because your product had a defect in it --  
23 the regulations don't require perfection, do they?

24 A They require that the product be within  
25 the defined and approved specifications. That's not

1 perfection. It doesn't need perfection. But you have  
2 to make it the way you say you'd make it.

3 Q If you're counseling one of your -- well,  
4 let's back up. You've been consulting and giving  
5 counsel to pharmaceutical manufacturers for 13, 14 years  
6 since you left the FDA?

7 A Fourteen.

8 Q Okay. You've been involved in  
9 circumstances where they conduct investigations into out  
10 of specification results?

11 A Yes.

12 Q You don't always find a root cause, do  
13 you?

14 A No, once in a while you don't. But you  
15 have to exert a certain amount of effort to look into  
16 it.

17 Q You have to try.

18 A Uh-huh, yes.

19 Q But it's certainly possible and it happens  
20 that you can do a completely thorough investigation into  
21 the circumstances you're involved with and not determine  
22 the root cause for why that happened.

23 MR. MILLER: Objection, asked and  
24 answered.

25 A It is possible and it happens once in a

1 while.

2 Q Okay. And the industry as a whole is  
3 based on sampling protocols, right?

4 A The industry is based on sampling -- the  
5 industry uses sampling protocols.

6 Q Well, and --

7 A Or is --

8 Q Maybe we're saying the same thing.

9 A I'm not questioning your choice of words,  
10 but maybe reword it.

11 Q Well, maybe we're saying the same thing.  
12 The release decision was used -- or the release decision  
13 made by all companies in the industry are -- they use  
14 sampling protocols to make those release decisions.

15 A Take your samples of whatever you're  
16 sampling for analysis to get your data.

17 Q You don't test every --

18 A Not a hundred percent.

19 Q -- individual tablet or -- and let's stick  
20 with tablets. You don't test every tablet for  
21 compliance with all specifications.

22 A Correct.

23 Q And does any company test every tablet?

24 A You wouldn't have anything left to sell.

25 Q Not very economically viable.



1 A Not economically viable.

2 Q So the industry is based on sampling  
3 protocols.

4 A Correct.

5 Q Deviations during a -- you talk in your  
6 article about, the top of page 5, Corrective Action and  
7 Preventive Action. And you advise in the article that  
8 you should request CAPA, C-A-P-A, records for the time  
9 period that includes the production of the questionable  
10 lot. If something happened during production that  
11 differed from approved procedures, this will be noted as  
12 a deviation, which the company must investigate.

13 Did I read that correctly?

14 A Yes.

15 Q Deviations can occur during the  
16 manufacture of a batch and a batch can still be released  
17 properly, correct?

18 A If the deviation was investigated  
19 according to your protocols or procedures and found to  
20 be acceptable, it can occur.

21 Q Okay. And you counsel manufacturing --  
22 companies that manufacture pharmaceuticals. You run  
23 into, I would assume fairly regularly, deviations that  
24 are properly investigated and the batch is still  
25 released.

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1                   A    Fairly regularly, yes, uh-huh. That's  
2   right.

3                   Q    So there's nothing -- well, strike that.  
4                    Going back to reviewing batch records, batch  
5   records will show whether a product was tested properly  
6   in the lab, correct?

7                   A    It will show theoretically everything in  
8   the production line including --

9                   Q    So you need to answer my question now,  
10   Mr. Farley.

11                  A    Yes.

12                  Q    It will show whether a product was tested  
13   properly in the lab.

14                  A    Yes.

15                  Q    It will show whether the results of that  
16   laboratory testing were within specifications.

17                  A    Yes.

18                  Q    If the FDA was conducting an inspection of  
19   a facility and wanted to determine whether the company  
20   had complied with Good Manufacturing Practices, it would  
21   review batch records, right?

22                  A    Yes.

23                  Q    And from that review would make a  
24   determination about whether the FDA believed, whether  
25   the inspector believed there was some non-conformance.

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1 A Yes.

2 MR. MILLER: Object to form.

3 Q And let me make that -- some  
4 non-compliance with Good Manufacturing Practices.

5 A That would be one of the things. They  
6 would have a whole schedule of things to look at of  
7 which batch record examination would be one.

8 Q When the FDA is -- well, never mind. I'll  
9 ask that later. You can also review SOPs to determine  
10 whether a company has complied with Good Manufacturing  
11 Practices.

12 MR. MILLER: Object to form.

13 A You look, A, for existence of the proper  
14 SOPs; and B, for the fact that they're using them and  
15 doing what they say.

16 Q Right. So there are two -- there's  
17 actually two forms of GMP compliance associated with  
18 SOPs. First, whether the SOP itself satisfies the  
19 minimum requirements of the regulation, right?

20 A Yes.

21 Q When it's drafted properly.

22 A Yes.

23 Q And second, whether you comply with the  
24 SOP during your manufacturing process.

25 A Yes.

1 Q And again, the FDA when it is inspecting a  
2 company for GMP compliance it might undertake both of  
3 those reviews.

4 A Yes.

5 Q It might review the substance of the SOP  
6 to determine whether it believes it meets the minimum  
7 requirements and it also might review the batch records  
8 to determine whether you actually have complied with the  
9 SOP during manufacturing.

10 A Yes.

11 Q You can't -- you can't determine whether  
12 you've complied with the SOP without reviewing the batch  
13 records.

14 A In the case you're talking about, correct.

15 Q Well, is there any case where you could  
16 determine compliance with an SOP without reviewing the  
17 batch records?

18 A They would be SOPs not relating to the  
19 batch, like the example you gave earlier.

20 Q Okay. Related -- well --

21 A I can't qualify my answer.

22 Q -- you can't determine -- and I apologize  
23 for talking over you.

24 A That's okay.

25 Q You can't determine whether you've

1 complied with an SOP that relates to the manufacture of  
2 a specific product without reviewing the batch records.

3 A That's your most sure way, yes.

4 Q Okay. If you were doing a consulting  
5 assignment that's what you could do?

6 A Definitely.

7 Q You wouldn't tell that company whether  
8 they complied or not without reviewing the batch  
9 records. That's being thorough like you described  
10 earlier.

11 A Correct.

12 Q How would you offer an opinion about GMP  
13 compliance with respect to manufacturing a specific  
14 product without reviewing batch records?

15 A How would I offer an opinion about --

16 Q Yeah.

17 A -- compliance?

18 Q You couldn't -- well, you couldn't  
19 offer -- you, Mr. Farley, as a consultant you couldn't  
20 offer an opinion about whether a company -- if a company  
21 came to you and said, I want to know whether we've  
22 complied with GMPs as we manufactured and released these  
23 batches of this product.

24 A Sure.

25 Q You could not undertake that exercise

1 without reviewing those batch records, right?

2 MR. MILLER: Object to form.

3 A I could not be assured of it without doing  
4 the batch records. And I would say in plain everyday  
5 terms, I want to see how it's made. And they would say,  
6 oh, we'll have the batch record for you right away.

7 Q And what if they said -- well, you  
8 wouldn't offer an opinion about whether they had  
9 complied with GMPs in manufacturing and releasing  
10 that -- those batches of that product without reviewing  
11 the batch records.

12 MR. MILLER: Object to form.

13 Q As you said earlier you'd say, I can't do  
14 that, I need to turn that down.

15 MR. MILLER: Object to form, misstates  
16 previous testimony, incomplete hypothetical.

17 A Could you give me the question again?

18 MR. ANDERTON: Could you read that back,  
19 please?

20 (The record was read back as requested.)

21 A I would have to review the batch records  
22 to render a complete opinion as to whether everything  
23 was done properly. Is that -- am I answering -- sure.

24 Q Okay. Go to the heading in your article  
25 Witnesses, page 6.

1 A I have it.

2 Q Take a look at the fourth full paragraph  
3 under that heading. It starts, When discussing. Do you  
4 see that?

5 A I'm with you.

6 Q And it reads, When discussing alleged  
7 violations the expert should be able to describe what  
8 should have been done and why and the difference that  
9 compliance with relevant GMPs would have made to the  
10 finished product.

11 He or she must connect the specific GMP  
12 violation to the negligence or defect that caused injury  
13 or loss. This causation connection is important as  
14 determining the GMP violations -- I'm sorry -- this  
15 causation connection is as important as determining the  
16 GMP violations because irrelevant GMP violations cannot  
17 establish the prima facie case.

18 Did I read that correctly with that little  
19 glitch in there where I went back and started that last  
20 sentence over?

21 A You read that correctly.

22 Q Okay. So you've got to have an expert  
23 witness identify specific GMP violations and they have  
24 to apparently -- well, you believe that they have to  
25 actually connect directly to a specific defect, correct?

1 MR. MILLER: Object to form.

2 A In order to correct it, yes.

3 Q Well, this isn't talking about correcting  
4 it, Mr. Farley. This article is about whether you can  
5 bring a lawsuit against one of these companies; and if  
6 so, how to do it, right?

7 A Right.

8 Q Okay. So the paragraph I read where you  
9 say -- where it reads, The expert must connect a  
10 specific GMP violation to the negligence or defect that  
11 caused injury or loss, you agree with that, right?

12 A Yes, I do.

13 Q And you also agree that irrelevant GMP  
14 violations -- and by irrelevant that means a GMP  
15 violation that doesn't actually relate to the defect  
16 that allegedly caused harm to a consumer, correct?

17 MR. MILLER: Object to form.

18 Q Is that what that means?

19 A It doesn't mean not important. It means  
20 not relevant to this situation.

21 Q Right. So you could have a GMP violation  
22 that doesn't speak to the -- or in any way relate to the  
23 defect that caused a consumer harm. That's what you  
24 mean when you use the term irrelevant GMP violations.

25 MR. MILLER: Object to form.



1           A    Yes. I had to hinge a bit when Gene, Jim  
2   and I were writing that about using that term, but we  
3   talked about it like we're talking now. It doesn't mean  
4   not important. It means not relevant to that path.

5           Q    Okay. What GMP violations can you connect  
6   specifically to Digitek?

7           MR. MILLER: And you feel free to pull  
8   out the documents and go through them a page at a  
9   time if you like.

10          A    Pretty much the -- all the 483s that were  
11   written. They mention one case. I'd have to get the  
12   483s to bring them out.

13          Q    We're going to get to those.

14          A    Okay. And they're -- now, they are  
15   printed.

16          Q    I've got plenty of copies. Don't you  
17   worry about that.

18          A    I'm sure. I would have guessed that.  
19   They're all listed in there. An observation on a 483,  
20   an observation of a particular GMP violation, and then  
21   there are examples given. It doesn't mean this is  
22   everything. Like here's the few examples of this  
23   observation which is a violation.

24               And I believe the inspection that concluded in  
25   May of 2008, I think it had 20 observations on it, which

1 was really a lot. I mean, that's a lot for a 483. And  
2 so their rule -- offhand I'd say they're all GMP  
3 violations on that document.

4 Q Well, we're going to talk about whether  
5 you're correct then that a 483 reflects any violations  
6 of anything.

7 A I would modify it slightly perhaps, but  
8 I'm sure there's a lot going on.

9 Q Modify it to what?

10 A I might say 18 out of 20 or something like  
11 that.

12 Q No. What --

13 A But right now I'm saying every one on  
14 there was a GMP violation.

15 Q And you said as you started to describe a  
16 483 and what's on a 483 that it lists what the inspector  
17 believes is a violation and then examples.

18 A Yes.

19 Q Is Digitek listed in all 20 or 18 of those  
20 examples on that 2008 483, do you remember?

21 MR. MILLER: Object to form of the  
22 question.

23 A I believe that not every one refers to  
24 Digitek. But to me reading it it relates to the overall  
25 system of quality assurance or a weak quality assurance

1 program. But in answer to your question, I don't  
2 believe every one in there refers to Digitek, per se.

3 Q Well, if you have an observation on a 483  
4 and you have examples, as a consultant to the  
5 pharmaceutical industry, if a company said, we'd like  
6 you to audit our records and identify all the products  
7 this observation relates to, you'd have to go look at  
8 the batch records, wouldn't you?

9 A I would.

10 Q So if an observation doesn't refer to  
11 Digitek, in order to determine whether that observation  
12 relates to Digitek you'd have to look at Digitek batch  
13 records.

14 A In order to determine if it related to  
15 Digitek, but I would have formed an opinion as to the  
16 overall system or management or the way the company  
17 runs. I mean, in plain words I might say this, this  
18 thing is all fouled up, I don't know what they can make  
19 right. I mean, that's plain terms but --

20 Q So that might be your initial thought, I  
21 don't know what they can make right, but then you'd go  
22 to the batch records and determine whether they did make  
23 it right.

24 A Yes, I would.

25 Q Okay. And if you didn't do that then you

1 can't say with any certainty whether the observation  
2 relates to any product where you didn't review the batch  
3 records, can you?

4 MR. MILLER: Object to form.

5 A It would relate to the product that the  
6 investigator listed. I would have to believe his or her  
7 statement on the 483. But to look at how much of it,  
8 I'd have to review.

9 Q Well, and to determine whether it related  
10 to any product that's not listed by the investigator you  
11 couldn't do that without reviewing batch records for  
12 that product, could you?

13 MR. MILLER: Object to form. We'd have  
14 to take a look at each one individual.

15 A Yeah. We would have to look at every one.

16 Q Every one what?

17 A Every product and all the batch records.  
18 I would have an idea as to whether it would or not by  
19 looking at that as I did look at the 483. But to be  
20 sure you'd have to go through each one of them.

21 Q And unless you did that you couldn't offer  
22 an opinion about whether it actually relates to each  
23 product.

24 A I could offer an opinion. I just wouldn't  
25 be sure of it.

1 Q Okay. And your opinion in that context  
2 without being sure would be speculation.

3 MR. MILLER: Object to form.

4 A If you use that term. I wouldn't want  
5 to -- I wouldn't want to take any of the firm's products  
6 until everything was investigated.

7 Q Okay. But, Mr. Farley, the answer to my  
8 question is, yes, it would be -- until you did that  
9 review it would be -- you could offer your opinion but  
10 it would be speculation.

11 MR. MILLER: Object to form.

12 A Speculation? Yes. Okay. Yes.

13 MR. ANDERTON: What have we got?

14 THE VIDEOGRAPHER: Eight minutes.

15 MR. ANDERTON: Eight? I'm not going  
16 to -- we're almost getting about to a breaking  
17 point. I'm going to talk to Ericka for a moment.  
18 So we're gonna step outside. If you'll just sit  
19 tight for a minute. We're within a couple minutes  
20 of a break.

21 THE WITNESS: Sure. Whatever you like.

22 MR. ANDERTON: But I want to --

23 THE VIDEOGRAPHER: Off record at 12:14.

24 (A brief recess was taken.)

25 THE VIDEOGRAPHER: Okay. We're back on

1 record. The time is 1:19 p.m. We did -- this is  
2 the beginning of Tape No. 4. We did conclude Tape  
3 No. 3 at 12:14 p.m. and we broke for lunch.

4 BY MR. ANDERTON:

5 Q Hello, Mr. Farley. Welcome back from  
6 lunch.

7 A Thank you.

8 Q You understand that you are still under  
9 oath?

10 A Yes.

11 Q Okay. And I want to just state, as I am  
12 admonished for not wearing my microphone, that,  
13 implicitly admonished, that while we were off the record  
14 you copied over to a portable thumb drive that I have  
15 with me all of the documents that were on your thumb  
16 drive and that relate to -- the thumb drive that we  
17 discussed earlier and that relate to the Digitek  
18 litigation and your engagement for Plaintiffs in this  
19 litigation. Is that correct?

20 A Yes, it is, in your presence and Peter  
21 Miller's presence.

22 Q Okay. So it is your understanding that  
23 all electronic documents that are on that thumb drive  
24 that relate to this litigation have now been placed onto  
25 my thumb drive?

1           A    You are completely up-to-date as of this  
2 minute --

3           Q    Okay.

4           A    -- on everything I have.

5           Q    And thank you for that.

6           A    You're welcome.

7           Q    Mr. Farley, what were you asked to do in  
8 the context of this engagement?

9           A    Essentially it was, Jim, we want you to  
10 evaluate some documents for us and assess the situation,  
11 there will be a court case, here's the product, here's  
12 the company, I want you to have some documents and  
13 render your opinion about this.

14          Q    Render your opinion about what?

15          A    About the status of the situation. These  
16 are my words, now. This is not a quote. I don't  
17 remember the -- I couldn't be quoted that part back.

18                But essentially what about this product and  
19 that company that makes the product, would you review  
20 these documents, give an opinion, at which time I said,  
21 well, I'll give you an electronic review of each  
22 document and then I'll render an opinion.

23          Q    When you say an opinion about the status  
24 of this product, do you mean the regulatory compliance  
25 status of that product? What do you mean by that?

1 A Did I use the word status?

2 Q You did.

3 A I didn't mean to use the word status.

4 About my evaluation of what this product is like and  
5 what the company is like.

6 Q Okay. So your evaluation of what the  
7 product is like and what the company is like with  
8 respect to what?

9 A Are they in compliance with FDA  
10 regulations.

11 Q Generally? Is that what you were asked to  
12 do, evaluate whether they were in -- whether this  
13 company, Actavis, is in compliance with FDA regulations  
14 generally?

15 A Most clients -- some clients will be very  
16 specific with you. Others will say generally and as  
17 specific as you want or tell me what areas you feel you  
18 should put -- you want to talk more about or whatever.  
19 It's essentially since I hadn't seen any documents, read  
20 these, give an evaluation to whatever depth you feel.

21 Q Okay.

22 A Those are my words.

23 Q I understand. And I need to have as clear  
24 as I can understanding with respect to an evaluation of  
25 what? I mean, what are you evaluating? What were you



1 evaluating as you read and reviewed the documents you  
2 were given?

3 A I was evaluating at a very minimum a  
4 product called Digitek and a company called Actavis --  
5 Actavis U.S. I believe it's called -- with regard to how  
6 well they can or cannot produce quality material.

7 Q With respect to Digitek specifically what  
8 were you evaluating?

9 A We looked at that one particular lot where  
10 we had the double thickness, but as time went on I  
11 looked more into the systems and began to realize that I  
12 wouldn't trust anything made by that company. I might  
13 have digressed a bit there.

14 But it was essentially, look it over and tell  
15 me what you find. I don't really have clients that --  
16 they don't tell me the answers they want. They tell me  
17 to look it over and tell me what you find. And then I  
18 say, I'll send you individual reports, individual files  
19 of each review.

20 Q Okay. But you were asked to look  
21 specifically at a product, Digitek, right?

22 A And the company.

23 Q That's two things, right?

24 A It was one project which involved a couple  
25 of different things.

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1 Q Two aspects of one project.

2 A Yes.

3 Q One of those aspects was evaluating  
4 Digitek.

5 A In my words can this company make Digitek  
6 right and can this company make anything right, in my  
7 words.

8 Q Can this company make Digitek right or did  
9 this company make Digitek right? What were you  
10 evaluating?

11 A Both.

12 Q So you evaluated whether the company  
13 properly manufactured Digitek?

14 A And whether I believe it is capable of  
15 doing it. I mean, it's more than one thing in the  
16 process.

17 Q I understand, Mr. Farley. Is one of the  
18 things that you evaluated whether Digitek was  
19 manufactured properly?

20 A Yes.

21 Q Is that also something that was the  
22 subject of your expert opinion, whether Digitek was  
23 manufactured properly?

24 A Yes.

25 Q Let's talk about FDA 483s for a moment.

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1 A Yes.

2 Q 483s -- well, you tell me what a 483 is.

3 A First I would like to define an  
4 observation is a violation.

5 Q Mr. Farley --

6 A Yes.

7 Q -- that wasn't close to the question I  
8 asked.

9 MR. MILLER: I disagree.

10 Q I asked you what a 483 form is.

11 MR. MILLER: But he's answering the  
12 question.

13 Start again where you were.

14 A I have to start with what an observation  
15 is because it's part of it.

16 Q I'm asking you what a form is. I didn't  
17 ask you what -- an observation is something that goes on  
18 the form.

19 A Oh. All right.

20 Q I asked you what the form is.

21 MR. MILLER: Well, if he's explaining to  
22 you what's on the form that's an answer.

23 Go ahead and answer just the way you were  
24 going to answer. Don't let him tell you how to  
25 answer a question.

1           A     Okay. Continuing on, the 483 is so called  
2     it because it's an FDA Form 483. But that form is a  
3     list of observations -- and I'm using that term  
4     interchangeably with violations -- that an inspection --  
5     an inspector or inspection team observes when they  
6     inspect a facility.

7           Q     Your testimony is that an observation on a  
8     483 reflects an actual violation of what? Good  
9     Manufacturing Practices?

10          A     Could be that.

11          Q     Could be what else?

12          A     A lot of times -- if it's a GMP inspection  
13     it -- if it's a GMP inspection, then it will be a GMP  
14     violation. There are pre-approval inspections. There  
15     are for cause inspections when someone says, hey, I  
16     think something is being done wrong at that plant. But  
17     if it's a GMP inspection then it will center on GMP  
18     violations.

19          Q     But it's not an actual final determination  
20     of violation of GMPs, is it?

21          A     It holds a lot of weight. It's the  
22     inspector's -- it's their jobs. They turn it in to a  
23     supervisory inspector. It goes to district director.  
24     Let me say it this way. In almost eight years at FDA  
25     I've never seen one changed.

1 Q You've never seen one changed?

2 A I haven't, not in the Philadelphia  
3 district, which is one of the busier districts.

4 Q Did you review the revised warning letter  
5 that was issued in this case?

6 A I did.

7 Q So revised means that it was changed,  
8 right?

9 A I should have reworded that and said I've  
10 never seen one lessened. But, no. 483 is a list of  
11 observations. Let's say that I'm walking through your  
12 plant and I make observations.

13 Now, once I leave your plant, having told you  
14 of these observations, there's absolutely no reason I'm  
15 going to change anything. They're observations.  
16 They're facts. They're not opinions. They're facts.

17 Q This is not a great -- well, but you keep  
18 wanting to insist that there -- I think you testified a  
19 moment ago that you use the term observation and  
20 violation interchangeably.

21 A I do.

22 Q That's not correct, is it?

23 MR. MILLER: Object to form.

24 A Yes, it is correct.

25 Q Well, I asked you and I don't think you

1 answered it directly.

2 A Okay.

3 Q An observation is not a final agency  
4 determination on whether the company has violated Good  
5 Manufacturing Practices, is it?

6 MR. MILLER: Objection, asked and  
7 answered.

8 MR. ANDERTON: It hasn't been asked and  
9 answered. He raised it unilaterally in responding  
10 to the question.

11 A Technically it's not. They're all subject  
12 to approval by the supervisory investigator. But I've  
13 never seen any supervisory investigator or district  
14 director change one.

15 Q But the answer to my question is an  
16 observation on a Form 483 does not -- does not represent  
17 the determination of the FDA as to whether GMPs have  
18 been violated.

19 A Yes, it does. It represents the opinion  
20 of that inspector or inspectional team who is  
21 representing the FDA.

22 Q Subject to review by several levels within  
23 the FDA.

24 A I think I maybe best say it if --

25 Q Is that true or not, Mr. Farley, before

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1 you -- you can answer that question.

2 A Not several levels, no. I wouldn't say  
3 several levels.

4 Q Two at least?

5 A Sometimes -- sometimes it's one.

6 Q FDA -- or observations on a Form 483 are  
7 written up by the inspector, the investigator, correct?

8 A Yes.

9 Q Not subject to review before they're  
10 issued?

11 A Not subject to review. Correct.

12 Q So they don't have to submit them to the  
13 compliance division, for example, before they're issued?

14 A Correct.

15 Q Mr. Farley, I'm going to hand you a  
16 document that's marked as Defendants' Exhibit 57. It's  
17 difficult to read the sticker.

18 A Yes.

19 Q Depending on your vision status it may be  
20 difficult to read some language we're going to ask you  
21 to read real quickly. But I'm going to give it a shot  
22 nonetheless.

23 A Okay.

24 Q Do you see that this is an FDA 483 issued  
25 to Actavis covering an inspection that occurred in

1 September of 2007?

2 A I see it.

3 Q Is this one of the documents you reviewed  
4 as part of your rendering an opinion in this litigation?

5 A I believe it is.

6 Q Okay. I'm going to read the fine print,  
7 if you will, right below the heading on the first page  
8 there. And I'll -- if you'll follow along.

9 This document lists observations made by the  
10 FDA representative during the inspection of your  
11 facility. They are inspectional observations and do not  
12 represent a final agency determination regarding your  
13 compliance.

14 Did I read that correctly?

15 A You read it correctly.

16 Q That language is on all FDA 483 forms,  
17 isn't it?

18 A Standard.

19 Q So on its face this document makes very  
20 clear that observations on a 483 are not the final view  
21 of the FDA with respect to whether a company has  
22 complied or not complied with Good Manufacturing  
23 Practices; is that correct?

24 A My opinion is it's not the final view.  
25 It's what they're going to do about the company. Let it



1 open, shut it down, ask them to recall. But it's not  
2 going to change their opinion about the company or  
3 whether they're in or out of compliance. What happens  
4 here, this then gets classified as OAI, VAI or NAI.

5 Q What's VAI mean?

6 A Voluntary action indicated.

7 Q That's a very positive outcome for an  
8 inspection, isn't it?

9 MR. MILLER: Object to form.

10 A Not really. NAI, no action indicated, is  
11 a positive outcome for an inspection. If you're a  
12 pharmaceutical firm you want everything to be NAI, no  
13 action indicated.

14 Voluntary action indicated means you're doing  
15 something wrong and they told you to make it right. But  
16 like a recall, technically it's voluntary. If you don't  
17 do it they're going to shut you down. But it's called  
18 voluntary.

19 And an OAI is official action indicated, which  
20 means if you don't do this we're really taking action  
21 immediately.

22 Q So, Mr. Farley, back to my question about  
23 this language, this form on its face says whatever is  
24 written on here is not final agency determination  
25 regarding compliance, doesn't it?

1           A     That's what it says to be polite, but why  
2     would they send someone out to inspect and write this on  
3     a form? They're not going to say, by the way, don't  
4     worry about it, we're not listening to what our  
5     inspectors say.

6           Q     I understand that, Mr. Farley.

7           A     The inspector carries weight with their  
8     opinions.

9           Q     I understand that. But at the end of the  
10    day it is the first step in a multi-step process that  
11    ultimately determines compliance.

12          A     It's probably in time invested 99 or more  
13    percent by weight right here in front of us right now,  
14    because the supervisory inspector gets the inspector,  
15    how is this, how -- now, the inspector has been talking  
16    on the phone in the meantime.

17          So the supervisory inspector knows, how is it  
18    going at such and such. Hey, I'm finding a lot of  
19    problems here, this is going to be a big one. So the  
20    supervisory inspector knows whether -- what to expect.

21          Then they come in. They look. Do you have it  
22    written up okay? Fine. Okay. Good. I mean, it isn't  
23    like you're going before a board of review that doubts  
24    the inspector.

25          Q     I'm not suggesting that the --

1 A Okay. I mean, I just wanted --

2 Q -- inspector won't have the support of the  
3 people above him or her in the hierarchy at the FDA.  
4 But it is not accurate to say that an observation is a  
5 violation because the form itself says otherwise.

6 MR. MILLER: Object to form. It  
7 misstates what the form says.

8 A Well, I jump to Observation 2 only because  
9 I can't read exactly Observation 1 because of the print.  
10 Observation 2, the written stability testing program is  
11 not followed. There's a violation of GMPs right there.  
12 I mean --

13 Q If it's true it could be a violation of  
14 GMPs. There are -- the company is permitted to respond  
15 to a 483, correct?

16 A They are permitted to.

17 Q And sometimes the company will submit  
18 facts and circumstances in response to the 483 that will  
19 result in an observation being withdrawn.

20 A I've never seen it happen.

21 Q Well, that just means that your experience  
22 isn't broad enough to have run into that, correct?

23 A That could be. Logically that could be.  
24 But I think I have reasonable experience and it would  
25 indicate that if it happens it's rare.

1 Q Well, it happened in -- with respect to  
2 this company, didn't it?

3 A Did it?

4 Q Yes.

5 A I haven't seen it.

6 Q The revised warning letter that you read  
7 removed an observation when compared to the initial  
8 warning letter.

9 A The revised warning letter was after they  
10 responded and perhaps corrected -- I don't know --  
11 perhaps corrected that.

12 Q Well, all warning letters are after they  
13 respond and correct.

14 A But I mean, suppose somebody says you have  
15 to straighten that out. You say, okay, I'll have that  
16 straightened out by next week. You have a violation at  
17 that time, but you straighten it out and you say, could  
18 you knock this off the letter, it doesn't exist anymore.

19 Q Mr. Farley, if it were that simple there  
20 would never be a warning letter, because everybody  
21 responds to a 483 and offers corrections in response to  
22 a 483. So why would a warning letter ever be issued if  
23 it were just as simple as it doesn't exist anymore?

24 A No. I'll tell you why.

25 MR. MILLER: Objection, misstates his

1 testimony.

2 A Because when you said everybody responds  
3 in a positive way, no, they don't. That's why some  
4 places are shut down. That's why there are consent  
5 decrees. That's why some people either don't know how  
6 or don't care. And so, no, not everybody responds to it  
7 in a positive way. They all like to think they do but  
8 they don't.

9 Q There are plenty of warning letters that  
10 are issued even though companies have responded in a  
11 positive way, correct?

12 MR. MILLER: Object to form.

13 A I'm not sure. I don't know the answer to  
14 that.

15 Q You're an expert in regulatory compliance.  
16 How can you not know the answer?

17 A I haven't read all the warning letters  
18 that were issued. I'd have to --

19 Q I'm not asking you to read all of them.  
20 I'm asking you based on your experience in holding  
21 yourself out as an expert in regulatory compliance,  
22 isn't it true that, that warning letters are often  
23 issued even though a company receives a 483, responds  
24 positively to the 483 and corrects the situation?

25 A I've never seen it happen and it should

1 not happen.

2 Q Never seen it happen?

3 A I have never seen it happen. I -- go  
4 ahead. Should I continue or --

5 Q The warning letters essentially say  
6 nothing more than what's in the 483, correct?

7 A The warning letter -- yes, it does say  
8 more. The warning letter says, you must respond in 15  
9 business days --

10 Q Substantively --

11 A -- or we're going to take further action.

12 Q Okay. But that's the threatening part of  
13 the warning letter. But with respect to the substance  
14 of the warning letter and what it says about the facts  
15 and circumstances or the alleged violations, it's  
16 identical to what's in the 483, isn't it?

17 A I wouldn't use the word identical.  
18 It's -- a district director who looks over the 483 that  
19 the inspector and supervisor inspector have presented to  
20 him or her and determines if a warning letter is  
21 appropriate, these people really have to shape up,  
22 they're really not doing it good, I've got to have it  
23 where they must respond to this in 15 business days or  
24 we're going to take some other action like seizure or  
25 we're going to adjoin them.

1 And it gives you a deadline and it reaffirms  
2 the importance of it. It's -- they're significant 483  
3 items. And by significant I mean they can cause harm or  
4 danger to the consumer, the patient.

5 Q Are you familiar with the phrase Turbo --

6 A It's a new --

7 Q -- finding?

8 A -- system for generating -- I'm familiar  
9 with the phrase, but they did not use it when I was  
10 there.

11 Q So you don't have any experience with it?

12 A Only in reading it and seeing it's a more  
13 standardized format.

14 Q So if you're familiar with it then you  
15 know that all observations on FDA Form 483s are  
16 pre-drafted and that FDA inspectors must select from a  
17 pre-drafted -- what word do I want -- a pre-drafted  
18 sentence or sentences, pre-drafted language, in order to  
19 express an observation on a 483?

20 MR. MILLER: Object to form. That only  
21 pertains to a small portion of observation.

22 MR. ANDERTON: That's simply not true,  
23 Pete.

24 Q Do you know that to be true, Mr. Farley?

25 A That it has a particular format, pick one?

1 Q Yes.

2 A I don't know all the details or all the  
3 forms, but I know that to be true.

4 Q Okay. So FDA inspectors go. They conduct  
5 an inspection. They make observations of things that  
6 they believe are not in compliance with Good  
7 Manufacturing Practices if it's a GMP inspection.

8 A Yes.

9 Q And they go and as they're preparing their  
10 483 and listing the observation they select from  
11 essentially a menu of observations and they must use one  
12 of those menu options; is that correct?

13 A Yes, much like the policeman does if he  
14 stops you for speeding. He's got to --

15 Q Okay. So the inspector is on a 483  
16 listing facts and circumstances that he or she believes  
17 violate the Act.

18 A Yes.

19 Q Isn't that the opinion of the inspector  
20 about whether there's a violation?

21 A The inspectors do not put opinions in a  
22 483. This is drilled into you your first week at the  
23 agency. You put facts in there, not opinions.

24 Q The facts you put there must in your  
25 opinion violate the Act. You have to exercise some



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1 judgment, right, if you're an inspector and you're  
2 creating a 483?

3 A I feel like I'm getting into a play on  
4 words here and at the same time I'm trying to answer  
5 your question.

6 Q Well, you used, Mr. Farley, the example of  
7 a police officer.

8 A Yes.

9 Q If you're speeding -- if the speed limit  
10 is 55 and the police officer clocks you --

11 A Yes. 75.

12 Q -- you're either above or you're not.

13 A Yes.

14 Q And with respect to an FDA inspector,  
15 they're making judgment, exercise in judgment, in that  
16 moment about whether something complies or doesn't  
17 comply, right?

18 A Yes.

19 Q Judgment is very subjective, isn't it?

20 A I wouldn't call it that. If -- I guess  
21 one of the classic examples that I really had, someone  
22 inspected a plant and saw a bird flying through. And he  
23 said, this is unsanitary.

24 Well, technically in his opinion it was an  
25 unsanitary situation with the bird flying through a

1 pharmaceutical manufacturing plant. And nowhere in the  
2 regulations does it say you shouldn't have a bird flying  
3 through, but it says appropriate hygienic material  
4 procedures must be there.

5 So an inspector goes in and looks, taking that  
6 somewhat way out analogy and coming down now and looks  
7 and says, this is the same initials of the analyst and  
8 the reviewer, that's a violation.

9 Now, I'm not calling that an opinion. I'm  
10 calling that a fact. But if you want to call it an  
11 opinion you can call it an opinion. But it's right  
12 there. It's right there in front of you. There's --  
13 here's the initials, here's the initials. And that's  
14 it.

15 I've seen a case where somebody turned a wrong  
16 valve and ruined a 300,000-dollar batch of material.  
17 Well, nobody said, well, in my opinion you might have  
18 turned a wrong valve.

19 He did it. It's right there. It's all logged  
20 in. It's a fact. You can't ship that material. You  
21 ruined it. You know, I believe there are facts and I'm  
22 very reluctant -- in fact I'm resisting using the term  
23 opinion.

24 Q You did -- when you talked about the bird  
25 example you said that the inspector who saw the bird

1 flying through the facility expressed his opinion that  
2 that was unsanitary.

3 A To show you that -- the fact is the bird  
4 went through, but there's nothing in writing that says  
5 the bird shouldn't go through. But I used the opinion,  
6 so --

7 Q Likewise, there is not necessarily  
8 anything in writing to suggest that somebody  
9 shouldn't -- well, if somebody turns the wrong valve  
10 there may not be something in writing to indicate that  
11 they shouldn't turn the wrong valve. They tell you  
12 which valve to turn, but there's no regulation that says  
13 don't turn the wrong valve.

14 A But there's an SOP that says turn that  
15 valve at that time, this valve at that time, that valve  
16 at that time. An SOP was violated. Therefore, it's a  
17 violation of GMPs.

18 Q When you talked about -- as you counsel  
19 clients in the industry do you tell them the Turbo  
20 language FDA inspectors are required to use to express  
21 an observation on a 483 don't always match up well with  
22 the facts and circumstances that caused the FDA  
23 inspector to write up that observation?

24 A No, I don't.

25 Q You've never told a client that?

1                   A    No.  I don't tell them that.  I just tell  
2   them it's a violation and how they should keep things  
3   right.

4                   Q    So you don't discuss the process of 483s  
5   and what's on them and how to respond to them.  Do you  
6   counsel clients on those subject matters?

7                   A    Oh, we discuss it.  Most of them know a  
8   whole lot about it from having been in the industry for  
9   years and years and years.

10                  Q    When -- as I understand your testimony,  
11   you said the use of Turbo observations -- Turbo language  
12   on observations on 483s, that practice started after you  
13   left the FDA?

14                  A    Yes.

15                  Q    How long after?

16                  A    I left in '96.  It might have started  
17   around 2000.  I'm not sure when it started.

18                  Q    Okay.  So it's been in place -- it was not  
19   in place up until three, four, perhaps five years after  
20   you left?

21                  A    Correct.

22                  Q    And what have you done to educate yourself  
23   about use of Turbo language as you hold yourself out as  
24   a consultant in the industry?

25                  A    I don't look at the Turbo program, per se.

1 I look at what is written, if in fact the client had a  
2 483 written. In many cases my clients didn't have a 483  
3 and they just want to make sure that everything is still  
4 okay with them.

5 So the language of the Turbo program is not a  
6 primary concern. The content, the meaning of what an  
7 inspection is, how you make a good product, that is.

8 Q Do you counsel clients who have also  
9 received 483s?

10 A Sometimes.

11 Q You have to look at the Turbo language  
12 when you do that, don't you?

13 A Yes, I do.

14 Q You have to give your client guidance on  
15 what it means, what to do about it in response, right?

16 A Yes, I do.

17 Q They pay you a couple hundred bucks an  
18 hour to do that, right?

19 A Yes.

20 Q When you're giving that guidance you don't  
21 ever say to a client, well, it's not really the Turbo  
22 language you look at, it's the specific facts and  
23 circumstances you have to deal with?

24 How do you deal with the fact that the Turbo  
25 language doesn't always necessarily match up very well

1 with the underlying facts and circumstances?

2 A They give you examples. Whenever they  
3 give you an observation they give you examples. And in  
4 the case of a client that had a problem, problem being  
5 non-compliance, a 483, I wouldn't do that over e-mail.

6 I'd say, when do I visit your plant, I want to  
7 see where this occurred, I want to see what's happening,  
8 I want to talk to the people that you have employed.  
9 That's -- I want to see for myself in addition to this  
10 so that I can match it up. And invariably it does match  
11 up.

12 Q Invariably?

13 A I haven't seen it where I saw something  
14 that disagreed with the 483.

15 Q Have you ever talked to FDA inspectors who  
16 were unhappy about the fact that in fact their choice of  
17 observation -- choices, I should say, of observation  
18 language, that they really feel their hands are tied  
19 because the facts and circumstances they observe aren't  
20 always covered very well or very squarely by the choices  
21 they have from the Turbo program?

22 A I haven't talked to any like that. I  
23 wouldn't be surprised if some do complain about that.  
24 There are people in workplaces complain about everything  
25 wanting to do something. But I haven't heard any of

1     them.

2                   Q     And your testimony is that you've never --  
3     that it's always true that the Turbo language used by  
4     FDA inspectors matches up with the facts and  
5     circumstances they cite?

6                   MR. MILLER:   Object to form, asked and  
7                   answered, misstates previous testimony.

8                   A     It's -- my experience has been that it's  
9     always true that for the language they use, wherever  
10    they got it, Turbo or wherever or whenever, has always  
11    matched up.

12                  Q     Okay.  I've handed you, Mr. Farley, a  
13    document that has been marked as Defendants' Exhibit 58.  
14    Have you seen that document before?

15                  A     I believe so.

16                  Q     That is the 483 issued at the end of the  
17    2008 inspection of Actavis Totowa?

18                  A     Yes.

19                  Q     Will you look at Observation 2, please?

20                  A     On the first page?

21                  Q     Yes.

22                  A     I have it.

23                  Q     It reads, Drug products failing to meet  
24    established specifications and quality control criteria  
25    are not rejected.  Did I read that correctly?

1 A You read it correctly.

2 Q The first example they give relates to  
3 Digitek and specifically to Lot 70924. Do you see that?

4 A The first line, A?

5 Q Yes, the first example, Example A.

6 A I'm with you.

7 Q Okay. Why don't you take a moment. You  
8 don't have to read it out loud. But go ahead and read  
9 through just to refresh -- if you've seen this before  
10 I'm sure you read that. But refresh your memory and  
11 read the contents of Paragraph A, please.

12 A Just A?

13 Q Yes, just A.

14 A I read it.

15 Q Can you tell me in there where it says  
16 products that don't meet established specifications and  
17 quality control criteria were not rejected?

18 A The observation is drug products failing  
19 to meet --

20 Q I'm talking where in Paragraph A.

21 MR. MILLER: Well, he's stating what the  
22 observation is. So allow him to answer your  
23 question, Mike.

24 Q Go ahead, Mr. Farley.

25 A I'm more or less setting a flow to my



1 answer. Can I still do that?

2 Q I apologize.

3 A The observation is drug products failing  
4 to meet established specifications and quality control  
5 criteria are not rejected. Now, I look at the bottom,  
6 no additional thickness testing or analytical evaluation  
7 of the double thick tablets. They didn't analyze it.

8 And no root cause was determined for the  
9 defect. However, the lot was released to the market by  
10 the quality unit in January of '08 following visual  
11 inspection. That's shoddy. That is really lousy for a  
12 pharmaceutical --

13 Q Mr. Farley --

14 A Oh, that's my opinion.

15 Q -- I asked you where in Paragraph A it  
16 indicates that a product that didn't meet established  
17 specifications was not rejected.

18 MR. MILLER: Asked and answered. He just  
19 told you.

20 MR. ANDERTON: No, Pete. He didn't come  
21 close to answering that question.

22 MR. MILLER: I disagree.

23 A I thought I did.

24 MR. MILLER: He gave you a perfect  
25 answer.

1           A    I thought I did.  They didn't do  
2 additional testing and they didn't do a root cause  
3 analysis under the CAPA, Corrective Action/Preventive  
4 Action portion of the GMPs.

5           Q    Wait.  They didn't do a root cause  
6 analysis or they didn't determine a root cause?

7           A    It says no root cause analysis and none  
8 was determined.

9           Q    Okay.  So it doesn't say -- wait, wait.  
10 Mr. Farley, I don't want you to get in a hurry here  
11 because this has to be precise.

12          A    Yes.

13          Q    It does not say no root cause analysis was  
14 conducted, does it?

15          A    It does not say that.

16          Q    It says --

17          A    It says no root cause was determined.

18          Q    So a root cause analysis was conducted;  
19 they just were unable to determine the root cause.  And  
20 as you testified earlier, that happens, correct?

21               MR. MILLER:  Object to form, misstates  
22 previous testimony.

23          A    On occasion but they didn't do an analysis  
24 of the material.  This is a powerful, dangerous -- they  
25 didn't analyze it.

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1 Q They didn't analyze what? The double  
2 thick tablet?

3 A Yes.

4 Q They analyzed them to tell that they were  
5 too thick and they rejected them.

6 A That's measurement.

7 Q Did those tablets go to market?

8 A No, but any responsible manufacturer would  
9 want to know is this double dose or is it the same dose  
10 disbursed. You want to know information about that to  
11 prevent it from happening.

12 Q Mr. Farley, I understand that. Did those  
13 double thick tablets go to market?

14 A To my knowledge, no.

15 Q They were rejected?

16 A But I don't know how many may have made it  
17 to the market that are not accounted for. That's what I  
18 wonder. That's --

19 Q That's --

20 A -- what they caught.

21 Q -- what you wonder?

22 A I wonder, yeah.

23 MR. MILLER: Well, that's what they  
24 caught. That's what he said.

25 MR. ANDERTON: It's not what they caught.

1 Pete --

2 MR. MILLER: That's what he said. Read  
3 it back.

4 MR. ANDERTON: He said it's what they  
5 wonder.

6 MR. MILLER: And then he says -- well,  
7 please read back his last answer.

8 MR. ANDERTON: He never used the term  
9 caught.

10 MR. MILLER: Please read it back.

11 (The record was read back as requested.)

12 MR. ANDERTON: Because there was nothing  
13 about caught.

14 MR. MILLER: There was a word caught in  
15 there actually. But it's on the record like she  
16 said. Let's keep going.

17 BY MR. ANDERTON:

18 Q Mr. Farley, we're going to walk through  
19 this. Okay?

20 A Okay. There was one out in the market. A  
21 lady, a nurse or somebody in one of the documents found  
22 it.

23 Q From this batch?

24 A I don't know at this instant what batch it  
25 was from, but it was an oversized Digitek that she was

1 distributing to patients in I'm going to say an old  
2 person's home, an aged home, aged facility. And she  
3 found it. And she contacted them.

4 Q What's the basis for that testimony? What  
5 is your basis for that testimony?

6 A The document I read.

7 Q Okay.

8 A It's in the documents that we copied.

9 Q Mr. Farley, so your -- well, let's focus  
10 on this for a moment. Okay? And I'd like you to stay  
11 focused on my question without interjecting your own  
12 testimony. Okay?

13 MR. MILLER: Objection, argumentative.

14 Q Mr. Farley, the first sentence, During the  
15 packaging of Digoxin tablets 70924 five double thick  
16 tablets were observed. That doesn't say anything about  
17 out of specification tablets not being rejected, does  
18 it?

19 A That one doesn't.

20 Q Quality assurance approved a 100 percent  
21 visual inspection of the 4.8 million tablet lot which  
22 resulted in an additional 15 double thick tablets.

23 Again, 100 hundred percent of the batch was  
24 inspected and they found 15 more tablets. That doesn't  
25 say anything about out of specification tablets not

1 being rejected, does it?

2 A That as you worded it does not.

3 Q I just read the sentence, Mr. Farley. I  
4 didn't -- it wasn't my wording. That's the wording of  
5 the FDA, right?

6 A Yes.

7 Q So that doesn't say anything about out of  
8 specification tablets not being rejected, does it?

9 A Yes.

10 Q Am I correct about that?

11 A You're correct.

12 Q Okay. Although quality assurance was  
13 aware of double thick tablet findings, the batch was  
14 then released based on AQL sampling which included  
15 visual inspection of 1,330 tablets.

16 Again, it does not say out of specification  
17 tablets were released to market, does it?

18 A It does not say that.

19 Q No additional thickness testing or  
20 analytical evaluation of the double thick tablets was  
21 conducted. Focusing on the double thick tablets, which  
22 you already said were rejected, that sentence doesn't  
23 say anything about out of specification tablets going to  
24 market, does it?

25 MR. MILLER: Objection, asked and

1 answered.

2 A It does not say anything about going to  
3 market.

4 Q Next sentence, no root -- well, or not  
5 being rejected, does it?

6 A Say that again.

7 Q Well, I -- never mind. We'll go to the  
8 next sentence. No root cause was determined for the  
9 defect; however, the lot was released to the market by  
10 the quality unit on January 28, 2008, following the  
11 visual inspection.

12 Again, it does not say out of specification  
13 tablets were released to market, does it?

14 A It does not.

15 Q Next sentence, No documented evaluation of  
16 the 89 -- approximately 89 lots that remained on the  
17 market at the time of the inspection. It doesn't say  
18 anything about out of specification tablets going to  
19 market.

20 A No, but it does in that sentence right  
21 there say they didn't bother checking the ones that are  
22 on the market to see if any got out.

23 Q It doesn't say defective tablets -- out of  
24 specification tablets were released to market, does it?

25 MR. MILLER: Object to form.

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1                   A    The way you have it worded it does not say  
2   that.

3                   Q    Okay.  It's not my wording, Mr. Farley.

4                   A    I know.

5                   Q    It's the FDA's.

6                   A    I know.

7                           MR. MILLER:  Your last statement was your  
8   wording.  It was -- you were not reading.

9                   Q    I'm talking about the sentence.  That  
10   doesn't say out of specification tablets were released  
11   to market, does it?

12                  A    Correct.

13                  Q    So no sentence in that observation that  
14   relates to Digitek says out of specification tablets  
15   were released to marketing; yet the observation, the  
16   Turbo language, says drug products failing to meet the  
17   established specifications and quality control criteria  
18   are not rejected.

19                  A    I see it.

20                           MR. MILLER:  Hold on.  He's reading it.

21                  Q    There's no question.

22                  A    There was no question.

23                  Q    Give me one second.  Mr. Farley, I'm going  
24   to hand you a document that has been marked as  
25   Plaintiffs' Exhibit 158.  We decided to leave some of



1 the numbering on some of the -- some, not all, of the  
2 prior exhibits.

3 Have you seen that document before?

4 A I believe so.

5 Q Okay. This is an EIR, Establishment  
6 Inspection Report, relating to a 2007 inspection of  
7 Actavis, correct?

8 A Yes.

9 Q And Actavis Totowa, I should say.

10 A Yes.

11 Q Tell me what an EIR is.

12 A EIR means, as you just said, Establishment  
13 Inspection Report. It would be analogous to industry  
14 when you have a trip report. When there is an  
15 inspection and there are no observations or violations  
16 there's always a report, Establishment Inspection  
17 Report.

18 And in many cases, many that I've seen where  
19 there was a detailed inspection and the Establishment  
20 Inspection Report is the inspector as the head of the  
21 inspection team telling this is what we did, this is  
22 where we visited, this is what we looked at.

23 And if there's an EIR and there's no  
24 observations, that's as far as it goes. If there are  
25 observations then they are in effect excerpted from

1 there and put into a 483. But that's -- before I  
2 digress too much, that's an EIR.

3 Q Well, that's actually not true, is it?  
4 Isn't the 483 issued at the close of the inspection?

5 A Yes.

6 Q At the close-out meeting?

7 A The typed-out version is not prepared at  
8 the close-out meeting. They are aware of what they're  
9 going to receive, but they may come back.

10 Q Is it your testimony really that the  
11 typed-out version of the 483 is not delivered at the  
12 close-out meeting?

13 A Not at the -- not in my experience, not at  
14 the very end of it. They -- the word is, we're having  
15 this typed up, it will be delivered to you. Now --

16 Q That makes me question your experience  
17 significantly, Mr. Farley.

18 MR. MILLER: Object to form.

19 A You're welcome to do that, but what I have  
20 seen is they say, we found this, we found this, they  
21 show the handwritten one, this is going back to get  
22 typed. That's my experience. And you're certainly  
23 welcome to question it, but I'll hold with it.

24 Q Can you turn to page 3 of Plaintiffs'  
25 Exhibit 158?

1 A I have it.

2 Q While you have it, do you see the -- why  
3 don't you hold Defendants' Exhibit 57, which is the 483  
4 that relates to this 2007 inspection, another document  
5 that I had given you previously.

6 A That one?

7 Q That's the one.

8 A All right.

9 Q Now, back to page 3 of the EIR, at the  
10 bottom, the second to last paragraph. It's not  
11 redacted. It begins, On 9/28/07 an FDA 483,  
12 inspectional observations, was issued to Mr. Apurva  
13 Patel, managing director.

14 A Yes.

15 Q So this indicates the 483 was issued at  
16 the close-out meeting.

17 A Then she did it in that case that day. I  
18 mean --

19 Q Will you look at -- well, she did the same  
20 thing for the 2008 inspection, didn't she?

21 A Could be district policy. District  
22 directors can choose their policy.

23 Q Okay.

24 A What I have seen is when they're shown  
25 written, they say we're going to come back. Now, when

1 they come back you may call that a close-out meeting or  
2 others have just said we're coming to deliver the 483.  
3 But I don't view that as any contradiction of what I  
4 said. It just makes it non-universal. But you're  
5 getting the 483 either way.

6 Q What you said and what you said in your  
7 report is that observations from the EIR end up in the  
8 483. It's actually the other way around. It's the EIR  
9 that's not issued until long after the inspection; isn't  
10 that right?

11 MR. MILLER: Object to form.

12 A No. It's not needed until after. If you  
13 have an inspection and you observed some good things and  
14 some bad things, you want to get the bad things out  
15 first to get them corrected and then you'll get the good  
16 things that are things they were doing well.

17 Q The good things would be an EIR, not the  
18 483, right?

19 MR. MILLER: Object to form.

20 A Good and bad things are in the EIR, if  
21 there are any bad things.

22 Q Mr. Farley, turn in the Establishment --  
23 in the EIR from the 2007 inspection. And again staying  
24 on page 3, do you see the first full paragraph?

25 A Which one?

1 Q On page 3 the first full paragraph. It  
2 begins on 9/5/07.

3 A I see it.

4 Q Okay. And it describes the purpose of the  
5 inspection. And the third sentence reads, I explained  
6 that the purpose of my visit was to provide follow-up  
7 coverage to Warning Letter No. 07-NWJ-06.

8 And then it goes on to say also  
9 pre-inspectional -- pre-approval inspectional  
10 coverage -- there's some redacted language that the FDA  
11 redacted -- as well as GMP inspectional coverage.

12 Do you see that? Did I read that correctly?

13 A I see it.

14 Q Did I read that correctly?

15 A Yes, you did.

16 Q Okay. So the purpose of this visit --  
17 this inspection, I should say, was to follow up on a  
18 prior warning letter; is that right?

19 A That's what it seems to be.

20 Q I'm going to hand you a document that's  
21 been marked as Plaintiffs' Exhibit 25. You see that  
22 this is a revised warning letter?

23 A Yes.

24 Q You see the number, the file number, on  
25 the face of the warning letter, 07-NWJ-06?

1 A Yes.

2 Q Is that the same warning letter referenced  
3 in this EIR --

4 A Yes.

5 Q -- that is Exhibit 58?

6 A Yes.

7 Q So this inspection was to follow up on  
8 this one?

9 MR. MILLER: Object to form, misstates  
10 previous testimony. You read it in there, as well  
11 as GMP inspectional coverage. You seem to be  
12 forgetting half the sentence.

13 Q One of the purposes of this inspection was  
14 to follow up on this warning letter; is that correct?

15 A Yes.

16 Q You said you've seen the EIR that's marked  
17 Exhibit 158, right?

18 A This one?

19 Q Yes, that's the one.

20 A I've seen it. I reviewed it. I don't  
21 remember everything at this moment, but please ask me  
22 any questions you like.

23 Q By reviewed it do you mean to say that you  
24 reviewed it in the course of -- is it one of the  
25 documents you received from the Miller Firm?

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1 A Yes.

2 Q Is it something you reviewed in preparing  
3 your expert report in this case?

4 A Yes.

5 Q Give me one second. All right. Will you  
6 turn, Mr. Farley, to page 25 of Exhibit 158.

7 A Page 25?

8 Q Yes.

9 A I have it.

10 Q Will you read the first heading on that --  
11 well, the first heading on that page reads Voluntary  
12 Corrections, right?

13 A Yes.

14 Q It goes on to read in the body of the  
15 paragraph under that, Corrections to the previous FDA  
16 483 were reviewed with Ms. Wanda Eng, senior director  
17 corporate compliance for Actavis. The previous 483  
18 observations in the associated corrections appear below.

19 A I see it.

20 Q So the FDA here is saying as part of this  
21 inspection we reviewed prior 483 observations and the  
22 corrective actions taken by the company, right?

23 A Yes.

24 Q And then they set forth pages of -- well,  
25 let's kind of go through some of this.

1 A All right.

2 Q On page 25 the first observation relates  
3 to the quality control unit and the authority of the  
4 quality control unit.

5 Do you see that?

6 A I see it.

7 Q And then under corrections it first  
8 indicates that a number of individuals have been hired.  
9 It lists several -- it looks like the better part of 15  
10 to 20 new hires. Do you see that?

11 A I see it.

12 Q On the next page, page 26, the first  
13 paragraph indicates that since the previous inspection  
14 the number of individuals in the quality assurance  
15 department has increased. It goes on to give the number  
16 but it's redacted. Do you see that?

17 A I see it.

18 Q And the rest of that page sets forth  
19 several paragraphs of additional corrective action,  
20 doesn't it?

21 A Seems to be.

22 Q Well, what do you mean seems to be? This  
23 is an FDA document, right?

24 A I have to read what we're correcting. I  
25 mean, the details. We said the quality control unit



1 lacks authority to fully investigate. Then we jumped  
2 over to details of what was observed and we went right  
3 to the corrections. So I -- before I answer your  
4 question I've got to know more of what we're correcting.

5 Q Please read the details.

6 A You or me?

7 Q You. You don't have to read them out  
8 loud. You can just go ahead and read the paragraph of  
9 Observation 1 on page 25.

10 A You want me read out loud or --

11 Q No, you don't have to read it out loud.  
12 Just read it and let me know when you're ready to answer  
13 questions.

14 A It will just be a minute.

15 Q Take your time.

16 THE VIDEOGRAPHER: Mr. Mike, while he's  
17 reading that I'm going to go off the record and  
18 change tape.

19 MR. ANDERTON: Okay.

20 THE VIDEOGRAPHER: It is 2:15 p.m.

21 (A brief recess was taken.)

22 THE VIDEOGRAPHER: All right. We're back  
23 on record. It's 12 -- pardon me. It's 2:22 p.m.  
24 This is the beginning of Tape No. 5.

25 BY MR. ANDERTON:

1           Q    All right. Mr. Farley, we were talking  
2   when we left about Exhibit 1 -- what has previously been  
3   marked as Plaintiffs' Exhibit 158, the 2007 EIR. And we  
4   were talking about information on pages 25 and 26 of  
5   that document.

6           Have you had the opportunity to read the  
7   observation language that you were reviewing on page 25?

8           A    Yes, I did.

9           Q    And so then after that observation  
10   language is a page and a half of actions that the  
11   company took in order to correct deficiencies that might  
12   have been reflected in that observation language; isn't  
13   that right?

14          A    I just pause. You said it might have been  
15   reflected. They're jumping out at me. That -- you're  
16   saying that might have been reflected. I'm looking at  
17   batches of drug products that have initially failed.

18          Q    Mr. Farley --

19          A    I mean --

20          Q    -- we're going to be here a long time if  
21   you don't start answering my questions. My question  
22   was, is there a page and a half of corrective actions  
23   set forth on pages 25 and 26?

24          A    Yes, there is.

25          Q    Okay. Documented by the FDA in this EIR?

1 A Yes, there is.

2 Q Okay. And accepted by the FDA?

3 MR. MILLER: Object to form.

4 A Implicit acception (sic) by the FDA since  
5 they wrote it.

6 Q Yes.

7 A Yes.

8 Q Next, page 27 -- well, let me ask you  
9 this, in the eyes of the FDA any deficiency that was set  
10 forth in Observation 1 is resolved by these corrective  
11 actions, right?

12 MR. MILLER: Object. It misstates the  
13 document.

14 A If they agree that it is resolved they  
15 could say -- and I'd have to refresh myself on the  
16 complete detail -- that here's your correction that you  
17 apply. They might say more is needed.

18 Q Do they say that with respect to  
19 Observation 1?

20 A I don't see it.

21 Q Okay. So in the eyes of the FDA any  
22 deficiencies that are reflected in Observation 1 have  
23 been corrected.

24 MR. MILLER: Object to form.

25 A An attempt has been made.

1 Q I'm asking you about --

2 MR. MILLER: Object. He answered.

3 A I wouldn't know if they were corrected  
4 until I saw the subsequent batches that were  
5 manufactured and if these people performed their jobs  
6 properly.

7 Q Mr. Farley, I'm talking about in the eyes  
8 of the FDA -- well --

9 MR. MILLER: Object, asked and answered.  
10 He said it's been attempted. That's what's been  
11 done. He gave you an answer. You're badgering  
12 him.

13 MR. ANDERTON: Pete, you're not going to  
14 just shout me down and allow him to avoid  
15 answering the questions I ask him.

16 MR. MILLER: I'm trying to shout over  
17 you, Mike. And you've already asked and answered.  
18 He gave you an answer.

19 MR. ANDERTON: He has not given me an  
20 answer --

21 MR. MILLER: He has.

22 MR. ANDERTON: -- to the question and  
23 we're going to stay here until he does.

24 BY MR. ANDERTON:

25 Q So, Mr. Farley, I asked you a question.

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1 You've acknowledged that there's a page and a half worth  
2 of corrective actions that the FDA indicates were  
3 taken --

4 A Yes.

5 MR. MILLER: Objection, misstates  
6 previous testimony.

7 Q -- right?

8 A That there appear they're taking some  
9 corrective action.

10 Q Okay. And the FDA wrote this document,  
11 correct?

12 A Yes.

13 Q So the FDA wouldn't write this if it  
14 didn't believe these things hadn't happened, right?

15 A Correct.

16 Q And that's based on the inspection that is  
17 reflected in this EIR, right?

18 A Correct.

19 Q So the FDA comes in, they review  
20 circumstances related to a prior observation to see  
21 whether corrective actions have been taken.

22 A Yes.

23 Q And they issue this document which sets  
24 forth all of these corrective actions, right?

25 A Yes.

1 Q And there's nothing in there indicating  
2 further action -- further corrective action is necessary  
3 for that observation, is there?

4 MR. MILLER: Objection.

5 A Nothing that I see.

6 Q Okay. Observation 2, page 27, do you see  
7 that language?

8 A Starting with laboratory records?

9 Q Yes.

10 A I'm reading it.

11 Q I don't want you to read it, but the  
12 observation is set forth and there are examples that go  
13 (a) through (g). Do you see that?

14 A Yes.

15 Q Again, that's language from a prior  
16 observation, right?

17 A Yes.

18 Q And on page 28 the FDA lists corrections.  
19 Do you see that?

20 A Top of 28?

21 Q Yes, sir.

22 A Yes.

23 Q So corrective actions were taken by the  
24 company in response to that observation, right?

25 A Yes.

1 Q Does the FDA indicate any further action  
2 is necessary?

3 A Not at that point.

4 Q Observation 3, do you see that on page 28?

5 A I see it.

6 Q And do you see that it sets forth five,  
7 (a) through (e), five examples that support that prior  
8 observation?

9 A Yes.

10 Q Do you see there are corrective actions  
11 indicated at the bottom of page 28 and continuing on to  
12 page 29?

13 A Yes.

14 Q Does the FDA indicate any further action  
15 is necessary to correct that observation?

16 A They do not.

17 Q Observation 4 on page 29, and you see that  
18 there are again five, (a) through (e), five examples,  
19 supporting Observation 4?

20 A I see it.

21 Q Do you see at the top of page 30  
22 corrective actions taken by the company?

23 A I see it.

24 Q Do you see -- does the FDA indicate any  
25 further action is necessary to correct that observation?

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1 A It does not.

2 Q Okay. Observation 6, still on page 30, do  
3 you see the observation?

4 A 6, bottom of 30?

5 Q I'm sorry. I misspoke, Mr. Farley. I  
6 jumped ahead and I apologize for that. Observation 5 in  
7 the middle of page 30.

8 A I see it.

9 Q Do you see that?

10 A Yes.

11 Q Do you see the corrective actions  
12 indicated by the FDA?

13 A I see it.

14 Q Does the FDA indicate any further action  
15 is necessary to correct that observation?

16 A They do not.

17 Q Observation 6 -- this time I mean it --  
18 starting on the top of page 30, continuing on to page  
19 31, and there are four specific examples, (a) through  
20 (d), supporting Observation 6.

21 Do you see that language?

22 A I see.

23 Q And do you see the corrections that the  
24 company took as indicated by the FDA in the EIR?

25 A I see it.



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1 Q Does the FDA indicate any additional  
2 actions are necessary to correct that observation?

3 A They do not.

4 Q I wish there was a way to make this  
5 shorter, Mr. Farley, but there is not. So I apologize.

6 A That's all right.

7 Q Mr. Farley, Observation 7 beginning on  
8 page 31, do you see that?

9 A I see it.

10 Q It carries over very briefly to page 32  
11 and then there are three paragraphs relating to the  
12 corrective -- or reflecting, I should say, the  
13 corrective actions taken.

14 Do you see that?

15 A Where are we here?

16 Q Now we're on page 32.

17 A I see it.

18 Q And do you see -- and, for example,  
19 Mr. Farley, do you see the very first sentence of the  
20 second paragraph of the corrections on page 32?

21 A Beginning with, Corrections to the  
22 stability program?

23 Q Yeah. Read that sentence out loud,  
24 please.

25 A Corrections to the stability program have

1 been verified during the current inspection.

2 Q So that's the FDA saying, we looked at  
3 this issue and we verified that the corrective actions  
4 have been taken, right?

5 A At that inspection, yes.

6 Q Okay. So does the FDA indicate any  
7 further actions necessary to correct the items set forth  
8 in Observation 7?

9 A No.

10 Q Observation 8, beginning on page 32.

11 A I have it.

12 Q Do you see that?

13 A I see it.

14 Q It carries over onto page 33 with -- again  
15 with five examples.

16 A I see it.

17 Q And then there are corrective actions  
18 indicated. Do you see that?

19 A I do.

20 Q Does the FDA indicate that there are any  
21 additional corrective actions necessary with respect to  
22 Observation 8?

23 A No.

24 Q Observation 9, beginning on page 33 and  
25 carrying over onto page 34 with three examples.

1 Do you see that?

2 A Yes.

3 Q And again, corrective actions indicated in  
4 a paragraph about one-third of the way down on  
5 Paragraph -- or excuse me -- on page 34.

6 Do you see that?

7 A I see it.

8 Q Does the FDA indicate that any further  
9 actions are necessary to correct Observation 9?

10 A They do not.

11 Q Observation 10, beginning on page 34  
12 actually and concluding on page 34. Do you see that  
13 observation?

14 A I do.

15 Q And there are corrective actions indicated  
16 on page 34 as well?

17 A Yes.

18 Q Any further actions necessary according to  
19 the FDA to correct that observation?

20 A No.

21 Q Observation 11, page 35.

22 A I'm with you.

23 Q Do you see any corrective actions  
24 indicated for Observation 11?

25 A I'm reading Observation 11.

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1 Q Take your time.

2 A Now I'm reading the corrections.

3 Q Take your time.

4 A And the question was?

5 Q Do you see any further actions necessary  
6 according to the FDA to correct Observation 11?

7 A No.

8 Q Observation 12 on page 36, do you see that  
9 observation?

10 A I see it.

11 Q And do you see the corrective actions  
12 indicated?

13 A I see it. I just want to read this one.

14 Q Take your time, Mr. Farley, whatever you  
15 feel is appropriate.

16 A I see it.

17 Q According to the FDA is that -- the items  
18 in Observation 12 corrected with no further action  
19 necessary?

20 A It appears to be.

21 Q Well, do they indicate any further action  
22 necessary to correct that?

23 A They do not.

24 Q And you said earlier that if there were  
25 further actions necessary they'd say that, right?

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1 A They would.

2 Q Observation 13, starting on page 36,  
3 continuing on to page 37, do you see that observation?

4 A I see it.

5 Q Do you see the corrective actions on page  
6 37?

7 A Yes.

8 Q Does the FDA indicate any further actions  
9 are necessary to correct Observation 13?

10 A No.

11 Q Observation 14, do you see that?

12 A Yes.

13 Q Do you see the corrective actions?

14 A I'm reading.

15 Q Take your time.

16 A I see them.

17 Q Does the FDA indicate any further action  
18 necessary to correct Observation 14?

19 A They do not.

20 Q And finally, Mr. Farley, Observation 15.

21 A Yes.

22 Q Do you see that beginning on page 37 and  
23 continuing over briefly onto page 38?

24 A Yes, I do.

25 Q Do you see the corrective actions

1 indicated?

2 A Yes, I do.

3 Q Does the FDA indicate any further actions  
4 are necessary to correct Observation 15?

5 A They do not.

6 Q So according to the FDA, corrective  
7 actions were taken in response to every single  
8 observation from the prior inspection.

9 A Taken or proposed? They hired new people,  
10 but you haven't seen them perform.

11 Q Were taken -- Mr. Farley, let's talk about  
12 you going down your own paths like that.

13 A Okay.

14 Q Taken means hiring. If you tell the  
15 FDA -- if the FDA cites you for not having enough  
16 personnel and you hire additional personnel you've taken  
17 a corrective action by hiring additional personnel.

18 A Right.

19 Q You don't need to see them perform to have  
20 taken the first step of the corrective action.

21 MR. MILLER: That's a different question.

22 Why don't you ask him the question --

23 MR. ANDERTON: I didn't ask him that  
24 question. That's my point. He keeps interjecting  
25 his own thoughts.

1 MR. MILLER: He keeps interjecting an  
2 answer and you keep stepping on him. Why don't  
3 you try asking a question and he'll answer the  
4 question.

5 MR. ANDERTON: I did ask him a question.

6 MR. MILLER: Well, ask him again.

7 MR. ANDERTON: Can you read the question  
8 that I asked before that back, please?

9 (The record was read back as requested.)

10 MR. MILLER: Can you read what the answer  
11 was, please?

12 (The record was read back as requested.)

13 MR. MILLER: And he was cut off. Would  
14 you like him to continue with his answer?

15 MR. ANDERTON: No, because he starts  
16 talking about them performing. That's not part of  
17 the corrective action. If the FDA --

18 MR. MILLER: Hiring somebody and their  
19 performance isn't part of a corrective action?  
20 Well, if you're asking if they just simply did  
21 something and didn't care what the outcome was  
22 then he's answering your question.

23 MR. ANDERTON: Well, there's a very  
24 precise reason why I'm asking that, Pete.

25 MR. MILLER: Well, ask it and he'll

1 answer it.

2 MR. ANDERTON: I'm trying to get him to  
3 answer my --

4 MR. MILLER: You're trying to get the  
5 answer you want to get.

6 MR. ANDERTON: I'm trying to get him to  
7 answer my narrowly focused question.

8 BY MR. ANDERTON:

9 Q Did -- in the eyes of the FDA -- well, let  
10 me start that question over. According to the FDA  
11 corrective actions were taken in response to every  
12 single one of the prior 483 observations, correct?

13 A Yes.

14 Q And the FDA didn't indicate any further  
15 corrective actions necessary in response to any of those  
16 483 observations --

17 A They did not.

18 Q -- did they?

19 A They did not. Could I explain my  
20 seemingly roundabout --

21 Q I don't think that's -- I mean no  
22 disrespect, Mr. Farley, but I'll ask the questions and  
23 then --

24 A Okay.

25 Q -- you go ahead and respond.



1           A    I just felt there was something important  
2   that -- but we'll go with the flow here.

3           Q    When is the last time you were hired and  
4   retained by a pharmaceutical company to consult about  
5   GMP compliance?

6           A    Probably last year sometime.

7           Q    2009, is that what you mean?

8           A    Probably. I just don't remember. I'd  
9   have to go to their files.

10          Q    Could it have been before 2009?

11          A    Definitely it was before 2009. I think it  
12   might have been in 2009.

13          Q    Okay. I mean the last time. When is the  
14   most recent?

15          A    I don't remember that one offhand. I just  
16   don't, because I took a little time off to write the  
17   book and I did some other things. And I turned down a  
18   few. I really honestly don't know.

19          Q    Okay. And just so that we're clear, you  
20   understand what final agency determination is, right?

21          A    Yes.

22          Q    A 483 is not final agency determination on  
23   GMP compliance, correct?

24          A    Correct.

25          Q    Nor is an EIR; is that right?

1 A Correct.

2 Q In fact, a warning letter is not final  
3 agency determination, is it?

4 A Correct.

5 Q The FDA's perspective is to err on the  
6 side of caution as they engage in their regulatory  
7 activities, correct?

8 A I haven't heard it in those terms. If  
9 you're telling me that I would say that as a patient, a  
10 consumer, I would hope they would.

11 Q I'm asking you that as a regulatory  
12 consultant. Does the FDA approach its regulatory duties  
13 from the perspective of erring on the side of caution?

14 A The FDA as I have always seen its  
15 approaches is it don't err at all. They never  
16 mentioned -- if you're asking my perspective --

17 Q I'm not talking about err in the context  
18 of manufacturing pharmaceutical products. I'm talking  
19 about the FDA in performing its job.

20 For example, the FDA will ask a company to  
21 recall a product -- well, the FDA doesn't have to  
22 believe there is defective product in the market to ask  
23 a company to recall a product, correct?

24 A Do they have to? They don't have to.

25 Q They will ask a company to recall a

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1 product if they believe there's a possibility a  
2 defective product is in the market.

3 A If they believe there's a finite  
4 reasonable possibility that people can get hurt.

5 Q Well, that's not the question I asked,  
6 Mr. Farley.

7 A I'm really trying to answer it. I really  
8 am.

9 Q They'll ask a company to recall a product  
10 if they believe there's the possibility that there is  
11 defective product in the market.

12 MR. MILLER: Object to form.

13 A Yes.

14 Q You've seen that in your experience?

15 A Yes.

16 Q Mr. Farley, I'm handing you a document  
17 that has been marked as Defendants' Exhibit 39. And I  
18 will represent to you that it is a print-out of a  
19 posting on the FDA Web site. And you can see on the  
20 bottom right corner that it was accessed and printed on  
21 June 14th of this year.

22 A I see it.

23 Q Have you seen that posting on the FDA Web  
24 site previously?

25 A I don't believe so. I've seen a lot of

1     them, but I don't believe I've seen this.

2                   Q     I understand.  So you're not -- you don't  
3     think you have?

4                   A     Correct.

5                   Q     Will you read -- give me one second.  Will  
6     you read the -- do you see the heading that says, If a  
7     Manufacturer is not Following cGMPs are Drug Products  
8     Safe for Use?  It's about two-thirds of the way down the  
9     page, the first page.  Do you see that?

10                  A     I'm pointing to it.

11                  Q     Okay.

12                  A     I found it.  I see it.

13                  Q     I'm going to read the first paragraph  
14     under that heading.  If a company is not complying with  
15     cGMP regulations any drug it makes is considered  
16     adulterated under the law.  This kind of adulteration  
17     means that the drug was not manufactured under  
18     conditions that comply with cGMP.  It does not mean that  
19     there is necessarily something wrong with the drug.

20                  Did I read that correctly?

21                  A     You read it correctly.

22                  Q     Do you agree with that?

23                  A     Skeptically.

24                  Q     Skeptically yes?

25                  A     Let me think about that.  It does not mean

1 that there is necessarily something wrong. If I were  
2 writing that I would say -- this is if I were writing it  
3 and then -- that necessarily that there is something  
4 wrong but it may not be harmful.

5 There's something wrong because you didn't  
6 make it right; therefore something's wrong. That's what  
7 I would say. I disagree with the way this is worded.

8 Q So you would say it does not necessarily  
9 mean the product is unsafe.

10 A Or harmful, yes.

11 Q Or harmful.

12 A That's the way I would word that.

13 Q Okay. What's your understanding of why  
14 Digitek was recalled?

15 A Of why what?

16 Q Digitek was recalled.

17 A I believe that a lady died. I believe  
18 that there were numerous violations of GMPs and that  
19 there's no assurance that the product on the market  
20 wouldn't do harm. That's my opinion from what I've  
21 read.

22 Q You read that a lady died from Digitek,  
23 from taking Digitek?

24 A Somewhere I read it.

25 Q You read -- Mr. Farley, you read an

1 adverse event reflecting an event that was reported from  
2 the market in sometime around 2000 and you believe that  
3 had something to do with a product recall that occurred  
4 in 2008?

5 MR. MILLER: Objection. You're putting  
6 words in his mouth. That has nothing to -- it's  
7 not even closely related. You've grossly  
8 misrepresented what he said.

9 A Go back to your question. Why do I think  
10 it was recalled?

11 Q Yeah.

12 A Somebody died from it years before.

13 Q How many years?

14 A Eight or ten.

15 Q And you think that had -- that related to  
16 the recall?

17 A No, no. It wasn't the end of my sentence.  
18 And in reading inspections and warning letters and  
19 looking not just at Digitek but at the company itself, I  
20 really question whether they can make anything right the  
21 way they were set up.

22 I didn't -- I agree with the consent decree.  
23 They're not capable -- were not capable of making a good  
24 product themselves. No guarantee of it.

25 Q Well, let's talk about operating under a

1 consent decree. When you operate under a consent decree  
2 you're under incredibly close scrutiny, right?

3 A Yes. I have assisted firms operating  
4 under a consent decree.

5 Q Okay. Would you do me a favor and just  
6 close that laptop up? I don't need you distracted and  
7 there's no reason for it to be open anymore.

8 A Okay. I just --

9 Q I apologize.

10 A No, that's fine. It was distracting me,  
11 too. I just thought you wanted it on.

12 Q I don't need it on anymore.

13 A We're going to shut it down then.

14 Q Okay. Now -- all set?

15 A All set.

16 Q You say you've consulted for firms that  
17 have been operating under a consent decree.

18 A Yes.

19 Q Very close scrutiny when that happens,  
20 right?

21 A Yes.

22 Q Everything they do is watched.

23 A Yes.

24 Q If a company operating under a consent  
25 decree doesn't comply with GMPs, they're going to have

1 big problems, aren't they?

2 A That's right.

3 Q They're not going to be able to release  
4 product, are they?

5 A They can't release it themselves. They  
6 need a third party approval. They're determined to be  
7 incapable of releasing it themselves when they're under  
8 a consent decree.

9 Q Well -- so if they're releasing product  
10 under a consent decree then they are complying with Good  
11 Manufacturing Practices.

12 A I hope so.

13 Q Well, they either are or aren't, right,  
14 Mr. Farley?

15 A That's right.

16 Q So they are?

17 MR. MILLER: Object to form.

18 A They should be.

19 Q If they're not they're not releasing  
20 product.

21 A I wouldn't doubt that some firms have  
22 released product when they shouldn't have.

23 Q But the third party has to approve.

24 A Oh, with the third party. Yes. The third  
25 party is the consulting function, usually a group of



1 many consultants, who will determine whether the  
2 material is good enough to be released to the market.

3 Q Well, and you indicated a few moments ago  
4 that when you're operating under a consent decree you're  
5 operating with a third party looking over your shoulder  
6 checking everything you do, right?

7 A Yes.

8 Q So if you're releasing product while  
9 operating under a consent decree with that third party,  
10 you're complying with GMPs, aren't you?

11 A For those batches of that product.

12 Q For the batches that get released.

13 A Yes.

14 Q Any batch that gets released while you're  
15 operating under a consent decree is GMP compliant.

16 A If it went through the third party, if you  
17 didn't do it on your own and sneak it out, which some  
18 firms have been known to do.

19 Q Assuming you didn't sneak product out the  
20 back door --

21 A You did everything right, then the answer  
22 is, yes, it should be good.

23 Q So when you're operating under a consent  
24 decree for a long period of time you're actually  
25 engaging in sustained GMP compliance, aren't you?

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1           A    While you're still trying to repair all  
2   your systems and get them in shape to do it yourself.

3           Q    The answer to my question is yes.

4           A    Yes.

5           Q    You're operating under sustained GMP  
6   compliance, right?

7           A    Yes.

8           Q    Let's go back to the Digitek recall.  You  
9   made -- when I asked you why Digitek was recalled you  
10   insisted on referring to somebody dying eight or ten  
11   years before the 2008 recall.

12           Do you believe that is one of the factors that  
13   resulted in Digitek being recalled?

14           A    For the current recall?

15           Q    Yeah.

16           A    I believe it may have been in the minds of  
17   FDA when they asked Digitek to recall, but I don't know  
18   that.  I have no way of knowing what was in FDA's mind  
19   other than the fact that they felt the product was  
20   unsafe.

21           Q    Well, let's see if we can figure out  
22   what's in FDA's mind on that issue.

23           A    Okay.  I mean yes.

24           Q    Mr. Farley, I have handed you a document  
25   that has been marked Defendants' Exhibit 38 and it is

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1 again a print-out of a posting from the FDA Web site.  
2 The date it was accessed and printed is June 15, 2010.  
3 And the title of the posting is "Facts and Myths about  
4 Generic Drugs".

5 A I see it.

6 Q Have you seen this posting before?

7 A No.

8 Q You have not?

9 A No.

10 Q Okay. Why don't you turn to page 2 of  
11 that print-out. And I'm going to read the first myth.  
12 This is a sheet, Mr. Farley, that -- it's kind of a  
13 publication put out by the FDA where they set forth  
14 something that might be part of public perception and  
15 then they set forth facts that the FDA believes kind of  
16 prove that perception incorrect.

17 A Yes.

18 MR. MILLER: Object to form.

19 Q Do you agree with that?

20 A I hear what you're saying.

21 Q Do you agree with that?

22 A That the FDA is putting this out to  
23 educate the consumer?

24 Q Yes.

25 A Sure.

1 Q Okay. So -- and the education that's  
2 occurring is the FDA making an effort to correct  
3 misconceptions that might be out there.

4 MR. MILLER: Object to form.

5 Q Do you agree with that?

6 A That's what it says.

7 Q Okay. So let's look at page 2. Here is  
8 the myth the FDA is addressing in this instance. There  
9 are quality problems with generic drug manufacturing. A  
10 recent recall of generic Digoxin, paren, called Digitek,  
11 closed paren, shows that generic drugs put patients at  
12 risk.

13 Did I read that correctly?

14 A You read it correctly.

15 Q All right. That's the myth according to  
16 the FDA. The fact according to the FDA is, quote, FDA's  
17 aggressive action in this case demonstrates the high  
18 standards to which all prescription drugs, generic and  
19 brand name, are held, closed quote.

20 Did I read that correctly?

21 A You read it correctly.

22 Q I'm going to go on and there are four  
23 bullet points under that fact that the FDA set forth.  
24 And the first one reads, In March 2008 FDA performed a  
25 scheduled inspection of the Actavis production facility

1 and identified products that were not manufactured to  
2 required specification over a period of time extending  
3 back to the year 2006. Included in this list of  
4 products was one particular lot of Digitek.

5 Did I read that correctly?

6 A You did.

7 Q Does that give you some insight into why  
8 the FDA started thinking about asking to recall that  
9 product?

10 A I'm not relating it yet.

11 Q Okay. Well, so far they're only talking  
12 about one lot, right?

13 A Yes.

14 Q And according to the FDA they encountered  
15 products not manufactured to required specifications and  
16 only one lot of Digitek fell under that description,  
17 right?

18 A Yes.

19 Q Okay. It goes on in Bullet Point 2 to  
20 read, Actavis detected a very small number of oversized  
21 tablets in this lot, paren, specifically, comma, 20  
22 double sized tablets in a sample of approximately 4.8  
23 million tablets, closed paren, period.

24 Did I read that bullet point correctly?

25 A Yes.

1 Q So the FDA is still talking about only a  
2 single lot, correct?

3 A Yes.

4 Q 20 tablets out of 4.8 million. Is that a  
5 lot?

6 A Is it a lot? Numerically it's not a lot.

7 Q Statistically is it a --

8 A But I wouldn't want to be the one to take  
9 the oversized tablet.

10 Q Understood. But statistically is it a  
11 statistically significant number, 20 out of 4.8 million?

12 A A statistician -- and I'm not a  
13 statistician -- would probably say, no, it's not  
14 statistically relevant. But as a person in the  
15 pharmaceutical industry I look at a drug like this and I  
16 say everything counts.

17 It's like saying, well, some of the parachutes  
18 won't work. Well, I want one that works. I mean, I --  
19 your question to me is very serious. And it is  
20 relevant. To a statistician it may not be.

21 Q Understood. Next bullet point -- and I  
22 misspoke. I said four. There's actually five. Next  
23 bullet point, quote, Although Actavis attempted to  
24 remove the affected Digitek tablets through visual  
25 inspection FDA determined that this method of removal

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1 was inadequate to assure the product's quality and  
2 consistency in accordance with the current Good  
3 Manufacturing Practice, and then cGMP in parentheses,  
4 regulations, closed quote.

5 Did I read that correctly?

6 A Yes.

7 Q So the FDA is focusing on the inspection  
8 method with respect to the double thick tablets for that  
9 single batch, right?

10 A Yes.

11 Q Having read those three bullet points,  
12 does that give you a better sense of why the FDA asked  
13 Actavis to recall this product?

14 A No, it doesn't really -- what it does, the  
15 first thing I see was shocked that they mentioned  
16 company names in here in what's supposed to be a public  
17 document.

18 Q Mr. Farley --

19 A They shouldn't do that. Yes.

20 Q -- that wasn't even remotely close to  
21 answering my question. Now, I would ask that you  
22 please --

23 A Okay.

24 Q -- answer my question.

25 A I will try. Please answer it -- I mean --

1 MR. ANDERTON: Would you read that back,  
2 please?

3 (The record was read back as requested.)

4 A Does it give me a better sense than I  
5 have? No.

6 Q It gives a pretty detailed explanation of  
7 why the FDA -- what the FDA encountered and why they  
8 asked Actavis to recall Digitek. You're a consultant in  
9 this industry and those -- that doesn't tell you --

10 A Your question was does it give me any  
11 better sense than I had and my answer is no.

12 Q Well, you talked about a woman dying ten  
13 years before this recall and you talked about all kinds  
14 of other things.

15 The FDA is actually explaining why it asked  
16 Actavis to recall this product, isn't it?

17 MR. MILLER: Object to form.

18 A They're not telling the whole story. I  
19 believe the recall was based on systems not functioning,  
20 quality systems not functioning and quality assurance.  
21 Does this give me any better -- no, it does not.

22 Q Well, that's what you believe. This is  
23 the FDA telling the world why it asked for a recall on  
24 this product, right?

25 A But your question was does it give me any



1 clearer understanding. My answer is no.

2 Q When I asked you that question earlier you  
3 said, I don't know why the FDA asked for that. And my  
4 question now is, does it give you a better sense of why  
5 the FDA asked for it? I'm not asking you your opinion  
6 any longer. I'm still trying to get you to answer why  
7 the FDA asked for a recall on this product.

8 I asked you that question about five minutes  
9 ago before we started reading this document and you said  
10 you didn't know. Now having read these three bullet  
11 points I repeat my question.

12 Does it give you a better sense of why the FDA  
13 asked for a recall on this product?

14 A It does not give me a better sense than  
15 what I had, that previous sense being that all the  
16 systems were not functioning properly.

17 Q Mr. Farley, that was the reason you gave  
18 why you thought the product was recalled. When I asked  
19 you earlier why the FDA asked for it to be recalled you  
20 said you didn't know.

21 A If that's what I said then that's what I  
22 said.

23 Q Okay. You definitely said that. So this  
24 doesn't help you? I mean, are you now telling me that  
25 you think your reason and the FDA's reason are the same?

1           A    They would be similar, identical overlap  
2   or whatever.

3           Q    Why wouldn't the FDA say that? Why would  
4   the FDA make reference to a single lot and double thick  
5   tablets and the inspection protocol and the concern  
6   about the inspection protocol?

7           Why wouldn't they -- why would they fool the  
8   entire world with a public posting on its Web site  
9   available to anyone in the world and say, these things  
10   are the reason we asked for a Digitek recall, if in fact  
11   it was all of the things you believe?

12           MR. MILLER: Object to form, misstates  
13   previous testimony.

14           MR. ANDERTON: It doesn't misstate his  
15   previous testimony.

16   BY MR. ANDERTON:

17           Q    You may answer, Mr. Farley.

18           A    My answer is I don't know why they would  
19   do that.

20           Q    Well, you worked for the FDA. They're not  
21   in the business of disseminating bad information, are  
22   they?

23           A    They're not supposed to be, but this is  
24   surprising to me, this --

25           Q    Would you have liked to have seen this as

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1 you were doing -- preparing your report in this case?

2 A If it's relevant information. And it  
3 seems to be. But I don't know that I'd change my  
4 statement to you.

5 Q Well, it's relevant information, though,  
6 right?

7 A Yes.

8 Q And it gives the FDA's position on this  
9 recall, doesn't it?

10 A Yes.

11 Q Bullet Point 4, Since the detection of  
12 the -- and I'm reading quoting now -- Since the  
13 detection of the manufacturing problem FDA has been  
14 actively engaged with this company to ensure that all  
15 potentially affected lots of Digitek have been recalled.  
16 In our best judgment, given the very small number of  
17 defective tablets that may have reached the market and  
18 the lack of reported adverse events before the recall,  
19 harm to patients was very unlikely, closed quote.

20 Did I read that correctly?

21 A You read it correctly.

22 Q So did you consider adverse events -- the  
23 historical pattern of adverse events as you prepared  
24 your report in this case?

25 A I reviewed files relating to adverse

1 events.

2 Q You reviewed FDA 483s. Do you know how  
3 many adverse events for Digitek were received in, say,  
4 the five years before the recall?

5 A I don't know the exact number.

6 Q Because you didn't ask and you didn't  
7 review that information, did you?

8 MR. MILLER: Object to form.

9 A I didn't ask and review.

10 Q Would you have liked to have known as you  
11 were preparing your report that the FDA thought that  
12 harm to patients was very unlikely?

13 A I would like to know -- if I was talking  
14 to someone at the FDA I would like to say, how come you  
15 say it's very unlikely and you tell them to do a Class 1  
16 recall, which means that it's very likely? The Class 1  
17 recall means harm to the patient is likely and you put  
18 on your Web site, FDA. Who did you hire to put this  
19 out?

20 Q Harm to the --

21 A That's a contradiction.

22 Q A Class 1 recall means harm to the patient  
23 is likely if they get a defective tablet. You've got to  
24 put that step in there, right, Mr. Farley?

25 A And if you buy or use the product you have

1 a possibility of getting a defective tablet.

2 Q I understand. But you must first have  
3 defective tablets, right?

4 A Defective in any a number of ways --

5 Q Okay.

6 A -- not just oversized.

7 Q What other defect are we talking about?

8 A It could be over-strength, under-strength.  
9 I don't trust their results.

10 Q Don't trust whose results?

11 A Digitek -- or Actavis.

12 Q Does the FDA say anything about anything  
13 other than double thick tablets?

14 A No, they do not.

15 Q So the FDA was on site conducting an  
16 inspection and asked the company to recall that product,  
17 right?

18 A They asked them to do a Class 1 recall,  
19 which means that harm is likely. And whoever --

20 Q Harm because --

21 A -- does this says it's unlikely and it's a  
22 contradiction.

23 Q Okay. But, Mr. Farley, you didn't answer  
24 my question. The FDA was on site conducting an  
25 inspection and asked the company to recall this product,

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1 correct?

2 A Yes.

3 Q Asked them to recall all lots, right?

4 A Yes.

5 Q Here they are explaining the reason why  
6 they did that, referring only to double thick tablets in  
7 a single lot. Do you see that?

8 A Yes.

9 Q And yet you don't think that's the real  
10 reason the FDA asked for this recall?

11 A No. I see a contradiction between this --  
12 I read -- I see it. You showed it to me. It's right  
13 here. I see this and I see what I read and I see a  
14 contradiction. If it's unlikely why do a Class 1  
15 recall?

16 Q It's unlikely because it's unlikely any  
17 defective tablets made it to market, Mr. Farley.

18 A Then why would they do a Class 1 recall?

19 MR. MILLER: Wait. That's not a  
20 question. Wait for a question.

21 Q Mr. Farley --

22 A Yes.

23 Q -- you understand what a Class 1 recall  
24 is.

25 A Yes.

1 Q I mean, you're a consultant in this  
2 industry, right?

3 A Yes.

4 Q It's based more on the nature of the  
5 product --

6 A Yes.

7 Q -- than on the likelihood of there being  
8 defective product. If there's any -- we established  
9 earlier that if there's any possibility that defective  
10 product made it to market the FDA will aggressively ask  
11 for a recall, right?

12 A Yes.

13 Q And if you have a product that has -- that  
14 is of the right nature and characteristics and there is  
15 any possibility that defective product made it to  
16 market, then that becomes a Class 1 recall, right?

17 A If there's possibility of harm to the  
18 patients.

19 Q Right.

20 A There's Class 1, Class 2 and Class 3.

21 Q I understand. So this drug, the nature of  
22 it is such that if you get a defective tablet -- I don't  
23 think anybody disputes -- you could potentially be  
24 harmed.

25 Do you agree with that?

1 A Yes.

2 Q But the FDA is making very clear, again,  
3 in a public announcement regarding this recall, it made  
4 the request for a recall because there were 20 double  
5 sized tablets in a single lot.

6 A Uh-huh.

7 Q Do you see that?

8 A Yes.

9 Q So we now have a lot more insight into why  
10 the FDA -- when you first said I don't know and I  
11 introduced this document, we now know why the FDA asked  
12 for this recall, don't we?

13 A This contradicts what I read.

14 Q What you read was a recall announcement  
15 and combined with the general standards for a Class 1  
16 recall.

17 A Uh-huh.

18 Q I don't think the FDA is saying here if  
19 you've got a defective tablet there's no possibility  
20 you'll be harmed. But they're very clearly saying, we  
21 don't think you -- there's a likelihood that you got a  
22 defective tablet, aren't they?

23 MR. MILLER: Object to form. The  
24 document speaks for itself.

25 A That looks to be what they're saying. Who



1 signed it? Who wrote it?

2 Q It's posted on the FDA Web site. Do you  
3 think a computer hacker got in and --

4 A Not necessarily a hacker.

5 MR. MILLER: Objection, argumentative.

6 A But I would wonder really because the way  
7 that's written.

8 MR. ANDERTON: What time did we start  
9 this session?

10 THE VIDEOGRAPHER: This session was  
11 started at 2:22, sir.

12 BY MR. ANDERTON:

13 Q Mr. Farley, I've handed you a document  
14 that was marked in a prior deposition as Plaintiffs'  
15 Exhibit 106.

16 A Yes.

17 Q Do you see that?

18 A Yes.

19 Q You've seen that before?

20 A Yes.

21 Q It was a pretty significant document to  
22 you, wasn't it?

23 MR. MILLER: Object to form.

24 A Every document is significant to me.

25 Q Well, you gave this one a lot of weight

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1 when you prepared your report, didn't you, Mr. Farley?

2 A Let me glance through it.

3 Q Take your time.

4 A I'm reading -- one of my questions when I  
5 reviewed this was who wrote it. There's no signature.  
6 But I just mentioned that. I'm prepared to answer your  
7 question.

8 Q My question is, you gave this a lot of  
9 weight when you wrote your report, didn't you?

10 A I gave them all a lot of weight.

11 Q You gave this one particular weight.

12 A If you say so.

13 MR. MILLER: No, don't let him say so.

14 A I mean, I -- to my knowledge I looked and  
15 felt what I thought was important and I tried to look at  
16 everything as best I could. I'm not sure -- did I give  
17 it a lot of weight? I gave them all a lot of weight.

18 MR. ANDERTON: Did somebody take my copy?

19 Oh, there it is.

20 Q Your report contains an explicit analysis  
21 of this document in particular, doesn't it?

22 A Yes.

23 Q Okay. So I actually like your question,  
24 Mr. Farley. Who wrote this? Do you know?

25 A Are you asking me or are you agreeing --

1 Q I'm asking you.

2 A -- that's a good question? It's on  
3 Actavis' letterhead.

4 Q Do you know who wrote it?

5 A I do not know who wrote it.

6 Q You describe it in your report as  
7 correspondence. Do you know that it's correspondence?

8 A A memo, correspondence. I mean, it's from  
9 someone at Actavis reporting on a close-out meeting.

10 Q A close-out meeting is a meeting that  
11 occurs at the end of an FDA inspection.

12 A Yes.

13 Q And on page 20 -- I'm sorry. On page 17  
14 of your report you have an entire paragraph devoted to  
15 commenting about this. And in particular you focus on  
16 the term "total failure" that appears in the third full  
17 paragraph on page 1 of Plaintiffs' Exhibit 106.

18 Do you see that?

19 A Yes.

20 Q Your comment is, To have a total failure  
21 such as this indicates that there is no product of this  
22 company at that location that can be relied upon to be  
23 of the proper identity, strength, quality and purity  
24 acceptable to the FDA as being safe for the consumer.

25 A Yes.

1 Q You've said multiple times during this  
2 deposition that you believe -- that you didn't believe  
3 in anything that this company released, right?

4 A I wouldn't trust anything that company  
5 produced as being safe.

6 Q Is that because this document suggests  
7 there was a total failure of the quality system?

8 A That and -- well, pretty much all the  
9 documents contributed in one way or another to what I  
10 wrote. This one I quoted from.

11 Q What does total failure mean in the  
12 context of this document?

13 A No reliability on any of the steps in  
14 their production system.

15 Q Were you at this meeting?

16 A No.

17 Q Did you talk to anybody who attended it?

18 A No. That's why I quoted from it.

19 Q Well, you quoted --

20 A I wasn't there.

21 Q I understand. But do you know what the  
22 person who prepared these notes meant?

23 A I assume a total failure means total  
24 failure.

25 Q With respect to what?

1 MR. MILLER: Objection. The document  
2 speaks for itself.

3 A The production of pharmaceutical products.

4 Q That's not what this document says.

5 MR. MILLER: Take your time and read the  
6 paragraph.

7 A From the quality systems standpoint.

8 Q But total failure of what aspect of the  
9 quality systems? Does this document say that?

10 MR. MILLER: Object to form.

11 A Total failure means --

12 MR. ANDERTON: Pete, what's your --

13 A -- total failure.

14 MR. ANDERTON: -- objection on that  
15 question?

16 MR. MILLER: My objection is you're  
17 taking it out of context. You need to read the  
18 whole sentence. It's vague, asked and answered,  
19 argumentative. Let's take it from there.

20 MR. ANDERTON: Would you read my question  
21 back, please?

22 (The record was read back as requested.)

23 MR. ANDERTON: All those objections to  
24 that question, Pete? Really?

25 MR. MILLER: Yeah, leave them on there.

1           What the heck. You can keep asking.

2       BY MR. ANDERTON:

3           Q     So notwithstanding Mr. Miller's frivolous  
4     objections, I repeat -- I ask you to answer my question,  
5     Mr. Farley.

6           MR. MILLER: And he did.

7           A     Would you repeat the question, please?

8           MR. ANDERTON: Would you read it back,  
9     please?

10          (The record was read back as requested.)

11          A     I read total failure as total failure,  
12     meaning there's nothing you can rely on as doing what  
13     it's supposed to do. Now, if you say of what aspect,  
14     well, then we're talking about partial failure.

15          Q     But that's your read of this document.

16          A     That's my reading of this document. Total  
17     failure, I mean, you look at that and you say, this  
18     company isn't doing anything right.

19          Q     What context was this in? Were you there?

20          MR. MILLER: Objection, asked and  
21     answered.

22          A     I was not there.

23          Q     So you place -- to reach that conclusion  
24     you're placing heavy reliance on the words in this  
25     document?

1           A    I place heavy reliance on words of any  
2 document that comes to -- that's given to me to review  
3 and it's an exhibit. So, yes, I do, but not because of  
4 one thing or another, because it was there or anywhere  
5 else.

6           Q    We can agree, Mr. Farley, that your  
7 comments in at least Paragraph A on page 17 are based  
8 entirely on this document. Take your time.

9           A    I wrote it but I want to review it to be  
10 sure.

11          Q    Please take as much time as you think is  
12 necessary.

13          A    Section A was based on this document.

14          Q    Entirely?

15          A    Yes.

16          Q    In order to have a true understanding of  
17 the total failure comment in this -- that this document  
18 reflects was made in this meeting you have to be at the  
19 meeting and hear the context in which it was made,  
20 wouldn't you?

21          A    I believe that helps anywhere if you're  
22 present and you feel the full context. So I'll give an  
23 agreement, not just on this but any situation.

24          Q    So the answer to my question is yes.

25          A    Yes.

1 THE VIDEOGRAPHER: I'm going to go ahead  
2 and change tapes, sir.

3 MR. ANDERTON: Okay.

4 THE VIDEOGRAPHER: We're off record at  
5 3:20.

6 (A brief recess was taken.)

7 THE VIDEOGRAPHER: All right. We're back  
8 on record. It's 3:24 p.m. and this is the  
9 beginning of Tape No. 6.

10 BY MR. ANDERTON:

11 Q Mr. Farley, I'm going to hand you a  
12 document that has been marked as Defendants' Exhibit 20.  
13 I don't know whether you've seen that document before,  
14 but take a moment to look at it and let me know when  
15 you're ready to answer some questions about it. And I  
16 will let you read sections necessary to answer any  
17 questions I might ask.

18 A It doesn't look familiar, so --

19 Q Okay.

20 A Thank you.

21 Q Are you ready to -- you want to -- are you  
22 ready to talk about it or do you want to --

23 A I'd like to glance through it.

24 Q Take your time.

25 A This should be fast enough?



1 Q What's that?

2 A Am I going fast enough?

3 Q Are you ready to answer some questions  
4 about it?

5 A As you see I've not read it, but I think  
6 that I can -- if you'll grant me if I'm stuck I'll go to  
7 a section.

8 Q You may take, as Mr. Miller says and I  
9 agree with, you may take as much time as you think is  
10 necessary to answer any specific question.

11 A Then I say let's start when you're ready.

12 Q All right. So you say you don't think  
13 you've seen that before. Does your review change that,  
14 that opinion? Do you think you've seen this document  
15 before?

16 A I'm vague. I saw so many. I saw 93 of  
17 them. Some of them I could say definitely yes, maybe a  
18 few definitely no. I just don't know. I'd have to --

19 MR. MILLER: And if I could add something  
20 to that. This was just sent to me. I saw it for  
21 the first time last week. And I believe I brought  
22 a copy and there's probably a copy in Mr. Farley's  
23 file. But I just received it.

24 MR. ANDERTON: I understand that. I know  
25 that to be true. So that doesn't surprise me.

1 MR. MILLER: So I think he has a copy,  
2 but I don't think he's gotten a chance to actually  
3 read it.

4 MR. ANDERTON: Understood.

5 BY MR. ANDERTON:

6 Q And whether you've seen it before is more  
7 formal or substance than anything, Mr. Farley.

8 A Thank you.

9 Q Do you see and based on your experience in  
10 the industry and as a consultant in the pharmaceutical  
11 industry that this is an EIR relating to a 2004  
12 inspection of Amide Pharmaceutical?

13 A I see.

14 Q You agree with that, right?

15 A Yes.

16 Q Okay. And you know from your involvement  
17 in this case that Amide Pharmaceutical is -- was the  
18 predecessor to Actavis Totowa?

19 A Yes.

20 Q And they are the original holder of the  
21 NDA -- excuse me; I misspoke -- the ANDA for Digitek?

22 A Yes.

23 Q Will you turn to page 4 of this EIR,  
24 please.

25 A I'm there.

1           Q   And I'm going to read from the -- there's  
2   a heading, History of Business, slash, Operations. I'm  
3   going to read some of that paragraph. Amide  
4   Pharmaceutical, comma, Inc., is a privately held family  
5   owned organization which has been in operation since  
6   1983.

7           Divya Patel, comma, President, comma, stated  
8   that the company has undergone significant changes,  
9   especially following the consent decree of permanent  
10   injunction in 1992. The site was shut down for one year  
11   in 1992. The consent decree was lifted in 2001  
12   following successful demonstration of sustained cGMP  
13   compliance.

14           Did I read those several sentences, correctly?

15           A   Yes.

16           Q   In your report on page -- well, on page  
17   19, the fourth -- I'm sorry -- the third conclusion on  
18   page 19 that you offer reads, To be under a consent  
19   decree for more that -- and that's a typo I suppose --  
20   that should be than --

21           A   That's a typo.

22           Q   -- ten consecutive years is an indication  
23   of continuing serious problems with FDA regulations.

24           Do you see that sentence?

25           A   I see it.

1 Q Did I read that correctly?

2 A Yes.

3 Q Well, they weren't under a consent decree  
4 for more than ten consecutive years, were they?

5 A I believe it was nearly ten consecutive  
6 years. So more than would not be correct.

7 Q Okay. So that's inaccurate and you got  
8 bad information apparently.

9 A Apparently on that one.

10 Q Okay. And we talked earlier about what it  
11 means to be under a consent decree and you agreed that  
12 if you're under a consent decree you're actually  
13 engaging in sustained compliance with cGMPs, aren't you,  
14 with current Good Manufacturing Practices?

15 MR. MILLER: Objection, misstates  
16 previous testimony.

17 A You are obligated to have third party  
18 review and release any product you make.

19 Q You're ultimately performing all of the  
20 activities to put those products in the position where  
21 you offer them for that review and release, right?

22 A Through the third party. They're actually  
23 doing some of the work for you.

24 Q They're not running machines for you.  
25 They're not --

1 A They can.

2 Q -- testing products for you.

3 A They can.

4 Q The product is being manufactured and  
5 offered for release under your name, correct?

6 A Yes.

7 Q You're ultimately responsible for that  
8 product.

9 A Yes.

10 Q The third party doesn't have any  
11 responsibility.

12 A The third party has responsibility to you  
13 the pharmaceutical company. I wouldn't say they don't  
14 have any responsibility.

15 Q Your testimony -- I didn't say they had no  
16 responsibility. They're not ultimately responsible for  
17 the product in the market, for the quality of the  
18 product in the market. That responsibility always rely  
19 with you the manufacturer, correct?

20 A Ultimately, yes.

21 Q And your testimony -- and the record will  
22 reflect what you said earlier. But you said that if  
23 you're operating under a consent decree with that third  
24 party oversight your -- you must comply with Good  
25 Manufacturing Practices.

1 MR. MILLER: Object to form, misstates  
2 his testimony.

3 BY MR. ANDERTON:

4 Q Because otherwise -- if you're releasing  
5 product you must comply with Good Manufacturing  
6 Practices because you can't release it without  
7 compliance, right?

8 A That's correct.

9 Q And this EIR indicates that the reason the  
10 FDA agreed to lift the prior consent decree that wasn't  
11 ten years -- wasn't more than ten years as you indicate  
12 in your report, because of successful demonstration of  
13 sustained cGMP compliance.

14 Is that accurate?

15 A Yes.

16 Q So when you say if you're under a consent  
17 decree for more than ten years -- forget the fact that  
18 the time is wrong -- and that that's an indication of  
19 continuing serious problems, the FDA apparently  
20 indicates that you -- that this company actually was  
21 successfully demonstrating sustained cGMP compliance,  
22 right?

23 A Yes. However, my experience in assisting  
24 firms to work their way out of a consent decree is that  
25 it normally takes one to two years to do it. And even

1     though I said more than ten and it's nine plus, just  
2     under ten, that's still three or four times the normal  
3     amount.

4                 So while the third party is putting the  
5     approval on the product it leads me to wonder why does  
6     it take them so long, admittedly not over ten but just  
7     under ten, why does it take them so long to work their  
8     way out? That's what I'm wondering.

9                 Q     Well, and so that we're clear, you're  
10    offering a conclusion that there are continuing serious  
11    problems with FDA regulations in your report, but now  
12    here today you're wondering whether they had serious  
13    problems with FDA regulations? You're wondering why it  
14    took so long?

15                A     Wondering is a term I'm using in this  
16    discussion. I am very sure it had serious problems.  
17    They had trouble fixing them. And why does it take a  
18    firm more than eight years, more than nine years to  
19    repair something that other firms repair in one or two?

20                Q     What documents did you review that relate  
21    to Amide's manufacturing operations during the period  
22    1992 to 2002?

23                A     I would have to go through the whole list  
24    of the 93 to answer that question.

25                Q     Did you review any?

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1           A    I quite likely did.  It's all in the list  
2   in the report.

3           Q    Let's take a look at that.  Starting on  
4   page 8 of 27.

5           A    Yes.

6           Q    Mr. Farley, would you walk -- or work your  
7   way through the documents in that list -- and you  
8   testified earlier that this is the entire list of  
9   documents you reviewed to prepare this report, correct?

10          A    Yes.

11          Q    Will you work your way through that list  
12   and identify all documents that relate to or reflect  
13   manufacturing operations of Amide during 1992 to 2002?

14          A    Of Amide.

15          Q    Correct.

16          A    I'm going to skip --

17          Q    I want you to work your way through it and  
18   you can identify them.  You can do it however you like.  
19   But I want to know about every single one.

20          A    All right.  In order to identify them as I  
21   present them to you, should I point or name them or --

22          Q    You can name them.  You can simply name  
23   them.

24          A    I'm looking now for the name Amide as my  
25   key to answer your question.  I see the distributing



1 agreement, Mylan/Amide distributing agreement. I'm on  
2 the second page halfway down and I'm looking for  
3 complaint for permanent injunction and consent decree  
4 for permanent injunction. And I'm saying I believe that  
5 would be part of the answer, but I'd have to pull it up.

6 Q Well, I can represent to you that those  
7 two documents relate to Actavis in 2008 and not the  
8 Amide consent decree that we've talked about.

9 A I'll move right on.

10 MR. MILLER: I object to that.

11 A I'm on page 11, the second line or area  
12 of -- Amide's FDA inspectional history, March 23rd, 1992  
13 to March 31st of 2004.

14 Q Okay.

15 MR. MILLER: What was the number of that  
16 document?

17 THE WITNESS: Plaintiffs' 235.

18 A On page 13 near the top, Plaintiffs' 241,  
19 a letter from Jasmine Shah, Amide. Do you see where I'm  
20 pointing?

21 Q Yes. Is that -- is that during 1992 to  
22 2002?

23 A 2004 is later than 2002.

24 Q Okay.

25 A I was going to say the one immediately

1 following Plaintiffs' 128, but that's 2004, which is  
2 later than 2002. And the following one is 2004. Those  
3 three in a row relate to someone questioning Jasmine  
4 Shah and him answering them. But they're all after  
5 2002. I've done the table.

6 MR. MILLER: You indicated you were  
7 looking for the word Amide. You jumped over the  
8 word Amide in Tab No. 6.

9 MR. ANDERTON: Pete.

10 MR. MILLER: He indicated he was doing a  
11 word search.

12 MR. ANDERTON: Pete, do you want to let  
13 him testify?

14 MR. MILLER: I'm helping him with his  
15 word search.

16 MR. ANDERTON: You're helping him with  
17 his testimony.

18 MR. MILLER: No, I don't believe so. He  
19 was very clear, I'm going to go down the list and  
20 tell you every time I see the word Amide. He  
21 missed it. All right. Do you want facts or do  
22 you want --

23 MR. ANDERTON: Pete, I want you to not  
24 testify for him.

25 MR. MILLER: I'm not going to testify.

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1 You can go ahead.

2 MR. ANDERTON: We can give you an oath  
3 and have you sit in that chair if you like.

4 THE WITNESS: I didn't flip to that page  
5 because I'm not sure if I should or should not.

6 MR. MILLER: That's fine.

7 MR. ANDERTON: Which page?

8 THE WITNESS: Whatever he said that I --

9 MR. ANDERTON: You may flip to whatever  
10 page you like, Mr. Farley. I --

11 THE WITNESS: Apparently I skipped a  
12 Plaintiffs' something; although I thought I went  
13 down the whole list.

14 MR. MILLER: You indicated you were  
15 looking for the word Amide. And, Mr. Farley, you  
16 passed over the word Amide on Tab No. 6.

17 MS. DOWNIE: Of course, it's the wrong  
18 time frame.

19 MR. MILLER: I have no idea what time  
20 frame.

21 THE WITNESS: I passed over it. I passed  
22 over that because it was January of '07.

23 MR. MILLER: I have no idea of the time  
24 frame.

25 THE WITNESS: So I'm going to hold with

1           what I finished --

2   BY MR. ANDERTON:

3           Q    What you've identified?

4           A    Yes.

5           Q    There were four or five documents.

6           A    I lost count but, yes, there were a  
7   couple.

8           Q    Okay. And so let's look at those  
9   documents. The first one you identified is the very  
10   first one on page 8, the Mylan/Amide distributing  
11   agreement.

12          A    Yes.

13          Q    Well, will that give you any insight into  
14   where Amide was complying or having difficulty complying  
15   with FDA regulations?

16          A    That would not.

17          Q    The next ones you identified were 20 and  
18   21. And I will tell you that those have nothing to do  
19   with Amide but are instead the complaint and the consent  
20   decree for Actavis.

21                   MR. MILLER: And I'll object. The  
22   documents speak for themselves.

23                   MR. ANDERTON: Yeah, and what they say,  
24   Pete, is that they relate to Actavis in 2008, not  
25   Amide in 1992.

1 MR. MILLER: And I believe there's a  
2 little bit of repertory history in those  
3 documents. I don't have them in front of me, but  
4 I think the simple answer is the documents speak  
5 for themselves, Mike.

6 MR. ANDERTON: Okay.

7 BY MR. ANDERTON:

8 Q And the next one you identified was on  
9 page 11, Mr. Farley, Plaintiff's Exhibit 235. What is  
10 that document? Do you know?

11 A Amide's inspectional history.

12 Q Do you know what that is?

13 MR. MILLER: Why don't you allow him to  
14 get the document. He brought it for you.

15 Q As we sit here -- I mean, I have it if I  
16 want to ask you questions about it specifically. Do you  
17 know from looking at this document what it is?

18 A It says it's an inspectional history and  
19 it is quite likely an inspectional history. But to take  
20 that one out of 93 documents and answer specific  
21 questions would not be fair to give you an honest  
22 answer.

23 Q I understand. What is the next  
24 document -- well, is it accurate to say -- if you turn  
25 back to page 19 and that third conclusion, is there any

1 source of information other than the documents you just  
2 identified which would have allowed you to form the  
3 opinion reflected in that conclusion?

4 MR. MILLER: I'll object. In all  
5 fairness I think he ought to see that document  
6 before he's asked a question about it.

7 MR. ANDERTON: I'm asking him if there  
8 are any additional documents besides the ones  
9 you've identified.

10 A Not a document but the fact that it was  
11 just under ten years and such a long, long time to be  
12 under a consent decree, which is very expensive and  
13 embarrassing, that opens your eyes as soon as you see  
14 that.

15 Q It opens your eyes in as a consultant, an  
16 expert consultant in this industry, it would prompt you  
17 to want to see more information, wouldn't it?

18 A Yes.

19 Q And so before, as you said earlier, before  
20 you could opine about compliance issues for that period  
21 or any period, while the consent decree might open your  
22 eyes you'd say, I'd want to see more information, right?

23 A Yes.

24 Q Are you familiar with the FDA surveillance  
25 program?

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1           A    I've heard of it. And honestly at  
2   different times it's had different meanings over the  
3   years. So if you could tell me which surveillance  
4   program --

5           Q    Are you familiar with the fact that the  
6   FDA -- do you know what an FDA 484 is?

7           A    484?

8           Q    Yeah.

9           A    I'm not familiar with a 484.

10          Q    You're not familiar with a 484?

11          A    I'm not familiar with a 484. I may know  
12   it not as a 484. Sample request. Is that the sample  
13   request form?

14          Q    Yes.

15          A    I just didn't call it the 484. That's a  
16   sample request where they come in and take samples  
17   periodically and then analyze it.

18          Q    And test the product --

19          A    I just blanked out on the 484 number and  
20   in a matter of seconds it came to me.

21          Q    Okay.

22          A    I'm not one to memorize 4 numbers too  
23   much.

24          Q    That's okay.

25          A    But it did come to me.

1 Q Did Plaintiffs' lawyers tell you that  
2 Digitek was routinely tested by the FDA as part of its  
3 surveillance program?

4 A No, but it's not surprising that they  
5 would be.

6 Q Okay. But you didn't know that as you  
7 formed your expert opinion in this litigation?

8 A I would have assumed it. I mean, we did  
9 surveillance in Philadelphia. They went out to  
10 SmithKline and Merck, brought them in. That  
11 surveillance program apparently is the same surveillance  
12 program we're talking about. And the 483 is the sample.  
13 So, yes.

14 Q And your understanding -- well, do you  
15 have an understanding of the surveillance program that's  
16 conducted under the auspices of the 484s that allow you  
17 to take a sample? What is your understanding?

18 A There are periodic checks of samples as  
19 they would be going to the marketplace.

20 Q Samples taken from the market.

21 A In effect, random. We could use the term  
22 random.

23 Q Well --

24 A But I mean -- okay.

25 Q Are they ever taken from the market,



1 from --

2 A Yes.

3 Q -- a pharmacist?

4 A Sometimes from a pharmacist and  
5 sometimes -- and I'm pausing because there are imaginary  
6 people who will get a prescription. In other words, it  
7 will be John Jones. And there is no John Jones, but  
8 they may order it over the Internet and have a post  
9 office box.

10 And they'll take this prescription for John  
11 Jones, who is a non-existent person, but it represents a  
12 prescription that was obtained over the Internet or  
13 through other means and analyze it.

14 Q Alternatively, the FDA can just show up at  
15 a pharmacist and issue a 484 and take a sample, can't  
16 they?

17 A They can.

18 Q Okay. And they do.

19 A They can.

20 Q And they do.

21 A They do.

22 Q Okay. And they did that while you were  
23 employed by the FDA from time to time.

24 A They did.

25 Q And it sounds like your lab was involved

1 in testing some of those samples.

2 A That's part of what we did.

3 Q Okay. And so if you thought Digitek might  
4 be part of the surveillance program as you were  
5 undertaking your responsibilities in this engagement for  
6 this litigation, why didn't you ask to see documents  
7 related to that to see how Digitek had performed?

8 A It didn't occur to me. It didn't occur to  
9 me.

10 Q You were evaluating Digitek. Wasn't one  
11 of the things you might want to know, how the FDA came  
12 down in its surveillance -- or what the results of the  
13 FDA surveillance program relating to this product were?

14 A In retrospect any additional information  
15 could have been helpful, but I didn't feel it necessary.

16 Q So you had formed an opinion based on your  
17 review of a FDA document. You didn't actually want to  
18 be bothered with the facts of the product in the market.  
19 You just wanted to look at FDA documents.

20 MR. MILLER: Object to form.

21 A No. I would not put it that way.

22 Q How would you put it?

23 A I wouldn't be bothered to do it. I'm not  
24 in agreement with that choice of words. I was  
25 evaluating a situation. And I believe I had, after

1 asking for more and getting more, sufficient documents  
2 to do my evaluation. And I wrote it. Right here.

3 Q To formulate a thorough opinion, if you  
4 knew Digitek was part of the surveillance program and  
5 consciously chose not to ask for that information, do  
6 you feel you've given a thorough evaluation -- if one of  
7 your pharmaceutical clients asked you to evaluate one of  
8 its products and you thought about whether it was part  
9 of the 484, the surveillance program, wouldn't you ask  
10 them to see that information?

11 A Yes, I would.

12 Q But you didn't here?

13 A I didn't. I didn't know the surveillance  
14 program as it related to them. And I don't work for the  
15 FDA anymore. I would not have ready access to that  
16 information.

17 Q You can get it through FOIA.

18 A I can get what?

19 Q You can get it through FOIA.

20 A We come back to the fact that I thought I  
21 had sufficient information here.

22 Q But if you were counseling a client you  
23 wouldn't think you had sufficient information. You said  
24 you would want to see and ask for the surveillance  
25 program results, right?

1           A     Probably that would be my viewpoint if I  
2     were counseling a client, yes.

3           Q     Okay. So your analysis here is narrower  
4     because of the perspective you're taking.

5           MR. MILLER: Object to form.

6           A     If you're saying -- if you're Plaintiff  
7     versus Defendant and which one, you might -- I would  
8     probably think of other things in carrying out my  
9     assignment.

10          Q     Well, but I want to make clear, you said  
11     your analysis here is narrower and you don't -- there's  
12     information out there that you didn't consider and don't  
13     feel you need to consider because you're working for  
14     plaintiffs, correct?

15          MR. MILLER: Object to form.

16          A     I didn't say my analysis was --

17          MR. MILLER: It misstates previous  
18     testimony. While I'm objecting you've got to hold  
19     on until I'm done --

20          THE WITNESS: Oh, I'm sorry.

21          MR. MILLER: -- and then you can answer.  
22     I'm going to object. It misstates previous  
23     testimony. Now it's okay to answer.

24          A     I mean, I didn't say it was narrower. I  
25     think you said it was narrower.

1 Q Well, you said that there's information in  
2 the surveillance program that you would consider if you  
3 were evaluating a product -- well, let me back this out  
4 a little bit.

5 You'd consider the surveillance information --  
6 surveillance program information if you were consulting  
7 for a client in the pharmaceutical industry that said  
8 evaluate this product, right?

9 A I might.

10 Q You said earlier that you would want to  
11 see it and that you might.

12 A I would -- I might --

13 Q Are you changing your testimony now?

14 MR. MILLER: Object to form.

15 A I'm not changing my testimony. If I said  
16 I would I would.

17 Q Okay. And you would also want to see all  
18 of the regulatory documents that you reviewed in this  
19 case, right?

20 A Yes.

21 Q But if you were counseling plaintiffs in  
22 the context of this litigation you don't want to see the  
23 484 information because you thought about it and chose  
24 not to ask for it.

25 MR. MILLER: Object to form.

1           A    The reason to look -- to have one sample  
2    taken and analyzed and be found good doesn't tell me  
3    after reading all of this that the firm is not making  
4    unsafe material out there to have one sample. So it  
5    wasn't anything that would have any statistical  
6    relevance to me.

7           Q    What if it was more than one sample? What  
8    if it was part of the surveillance program year after  
9    year?

10          A    It's tough to pick a finite number, but  
11   the answer would be yes. If it got to the point where  
12   it was a statistically representative number, then, yes.

13          Q    Out of 152 what would be a statistically  
14   representative number?

15               MR. MILLER: Object to form.

16          A    152 what?

17          Q    Batches.

18          A    We would be looking at -- I'd rely on a  
19   statistician's answer for that. If you're asking for my  
20   opinion, my opinion would be I'd want a sample from  
21   every batch.

22          Q    That's not a statistically representative  
23   number. Your term, Mr. Farley, not mine.

24          A    Okay.

25          Q    So when you -- what would be a

1 representative sample sufficient to allow you to credit  
2 that?

3 MR. MILLER: Object to form, asked and  
4 answered.

5 MR. ANDERTON: It hasn't been asked. It  
6 hasn't been answered.

7 MR. MILLER: It has been asked and it has  
8 been answered.

9 BY MR. ANDERTON:

10 Q You may answer it.

11 A I believe I would not make that  
12 determination myself. I would ask a statistician,  
13 because the answer, I'm sure, would depend on whether it  
14 was one campaign making 150 lots straight on through one  
15 after another or whether they made 10 lots and then  
16 changed the equipment over and made something else and a  
17 few weeks later started making this material again and  
18 then stopped and start again. And that number would  
19 vary. And I would rely on the statistician for that.

20 Q And if it was a single campaign of 152  
21 straight batches, according to you would the number be  
22 higher or lower than if it was multiple campaigns of  
23 four batches and five batches and then three batches?

24 A If it was a single campaign right on  
25 through, same equipment, same everything, I would

1 believe the number would be lower --

2 Q Okay.

3 A -- than if they were disassembling the  
4 equipment, making something else, cleaning it,  
5 re-assembling for that.

6 Q Did you ask about any external testing of  
7 the recalled Digitek?

8 A Did I ask about any external testing?

9 Q Yes.

10 A External testing.

11 Q Yes.

12 A I did not. I looked for analytical  
13 results on the double thicks, but I did not ask about  
14 external testing.

15 Q Explain to me the significance of the  
16 analytical results on the double thick tablets. The 20  
17 tablets out of 4.8 million, what significance would that  
18 have?

19 A If, and especially this with a low  
20 therefore dangerous therapeutic index where a patient  
21 can overdose very readily, if it's double thick and  
22 double weight, is it the same amount of active  
23 ingredient and twice the excipients or is it a double  
24 strength tablet, because a double strength tablet could  
25 kill someone.



1 Q Okay. So your analysis would be intended  
2 to determine the potentially harmful effects of those 20  
3 tablets?

4 MR. MILLER: Object to form.

5 A Yes. I would do that in any case as good  
6 practice because knowing the analytical results helps  
7 you determine where along the line something went wrong.

8 Q I understand. But the point is it would  
9 help you determine the potentially harmful effects of  
10 those 20 tablets and perhaps allow you better insight  
11 into determining the root cause.

12 A Yes.

13 Q But it doesn't affect the potency of the  
14 other -- let's call it 4.8 million tablets, because 20  
15 out of 4.8 million leaves almost still 4.8 million.

16 A In theory it does and if the analytical  
17 results were all within specification by their sampling  
18 procedures, then theoretically they're all in the proper  
19 strength.

20 Q And those batch records you reviewed. But  
21 the double thick batch are the records you reviewed.

22 A Batch record, yes.

23 Q And no others.

24 A Did not see them.

25 Q Didn't ask for them. Didn't ask for any

1 additional batches, did you?

2 A I asked for a batch before and a batch  
3 after.

4 Q Did you get it?

5 A No.

6 Q Did you ask for any batches other than the  
7 batch before and the batch after?

8 A I said if we can't get the one immediately  
9 before and immediately after, get me one that was  
10 sometime before, the closer the better, and sometime  
11 after, the closer the better.

12 Q Didn't get those.

13 A Didn't get them.

14 Q Why not?

15 A I don't know.

16 Q How many times did you ask?

17 A Twice.

18 Q What were you told when you asked and  
19 didn't get them?

20 A We'll get them.

21 Q Didn't.

22 A Didn't.

23 Q Did that affect your opinion at all?

24 A Of what?

25 Q Well, of anything in this case. I mean,

1 you're giving expert testimony in the form of an  
2 opinion. You asked for information that you obviously  
3 thought might be relevant, or you wouldn't have asked  
4 for it, and didn't get it.

5 A I had less to work with, but I still had  
6 what I felt was a sufficient amount. I had a batch  
7 record, the batch that had the double thick tablets.

8 And there's -- when you do a project there's  
9 also it'd be nice to have this, nice to have this, this  
10 will be good. And some things if you don't have them  
11 you say, I can't go on without this. Others you say,  
12 I'll evaluate what I have.

13 Q The batch before and the batch after, if  
14 they had come in, if the records for those batches show  
15 everything within specifications how does that affect  
16 your opinion in this case?

17 A If that came in I will look to picture  
18 that whatever it was that went wrong that made that  
19 occurred at that particular point in time.

20 Q It was an isolated incident.

21 A I would tend to look that way, yes.

22 Q Okay.

23 MR. ANDERTON: How much time we got?

24 THE VIDEOGRAPHER: 25 minutes.

25 MR. ANDERTON: Okay.

1 BY MR. ANDERTON:

2 Q What discussions have you had with  
3 Mr. Miller or other Plaintiffs' counsel about the theory  
4 being pursued by Plaintiffs in this litigation?

5 A I'm not sure what you mean by the theory.

6 Q Well, when you sue somebody alleging  
7 you've been injured by their product, you have to have a  
8 reason for suing them. You understand that, right?

9 A Yes.

10 Q And, you know, I suppose it's lawyer speak  
11 a little bit, but when you bring a lawsuit, until it's  
12 been proven or proved you're pursuing a theory.

13 You understand now what I mean when I use the  
14 term theory?

15 A Yes.

16 Q All right. So what conversations have you  
17 had with Mr. Miller or any other lawyer for the  
18 plaintiffs in this litigation about the theory of  
19 liability being pursued by the plaintiffs in this  
20 litigation and specifically as it relates to what they  
21 think was defective about the Digitek?

22 A I can't recall the exact words of any  
23 discussions I had, but Pete Miller would say, what did  
24 you find, what are you coming up with, and, of course,  
25 when can I expect the report or the results; although I

1 try to get them promptly.

2 But I believe what I said to Pete Miller,  
3 Pete, this place is really fouled up at this time, I  
4 wouldn't trust anything coming out of it. And Pete  
5 would say, well, we're looking at that aspect of it, or  
6 something to that effect.

7 But I believe that I brought the subject up to  
8 him that you're talking about Digitek, but I wouldn't  
9 trust anything made in this company by these people at  
10 that time.

11 Q And the basis for that statement is your  
12 review of FDA regulatory documents, correct?

13 A Documents, the various things, a lot of  
14 different things that were -- it wasn't one violation  
15 over and over. It was different violations.

16 Q But all of those are set forth in FDA  
17 regulatory documents, right?

18 A Yes.

19 Q Because you didn't review any  
20 manufacturing documents for any product to reach your  
21 conclusion that this place is really fouled up, right?

22 A Other than that one batch record. And my  
23 conclusion was based on the various observations of the  
24 various 483s.

25 Q So your contention is based entirely on

1 comments set forth in FDA in the 483s and FDA regulatory  
2 documents.

3 MR. MILLER: Object to form.

4 A Mostly. There are some of the other  
5 things we discussed, I'm sure played a role, but  
6 predominantly the FDA documents, the inspection results.

7 Q This industry as we talked about earlier  
8 is based on sampling of finished product, right?

9 A The industry is based on it?

10 Q Or --

11 A I don't know if I would use that word.

12 Q That's a poorly-phrased question and I  
13 apologize.

14 A You said it.

15 Q The release of product into the market in  
16 this industry is based on sampling of finished product,  
17 right?

18 A Yes.

19 Q How do you assure -- how can you be sure  
20 that all product released into the market is within  
21 specification? Is there any real way to do that?

22 A Is there any real way to be sure that  
23 every individual tablet and the batches? To be sure you  
24 would have to test every tablet.

25 Q Right.

1           A    You do statistically representative  
2   sampling. And you have statisticians who know where the  
3   statistical tables are. When you're making this much  
4   take a sample, take it from here, take it from there.  
5   And you do your -- we call it representative sampling.  
6   You analyze that.

7           Q    So if somebody says, assure me every  
8   tablet in the market is within specification, is that  
9   possible?

10          A    Not without testing every sample. Now,  
11   when you say specification, specification for weight?  
12   For size? For analysis? For everything? For  
13   everything? The right excipients? The right active  
14   ingredient? The right strength? You would test  
15   everything and you would have nothing left to sell.

16          Q    So if somebody says, assure me that every  
17   product that you've already released into the market is  
18   within specification, that's not possible.

19          A    In an absolute sense, no. You would base  
20   it on your sampling and your test results.

21          Q    You'd go back to your batch records.

22          A    Uh-huh.

23          Q    You'd review the batch records and there  
24   would be nothing else you could do at that point, right?

25          A    Nothing else you could do with regard to

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1 the answer for the person?

2 Q Yes.

3 A You say, here's our batch, here's the  
4 results, it all tested well.

5 Q Right. Nothing else you can do, right?

6 A According to your procedures nothing else  
7 you would do.

8 Q Nothing else you could do other than --  
9 other than go test it all.

10 A Or test some more to any degree. But you  
11 likely wouldn't do that. You likely would say, here's  
12 the results that we had and this is statistical  
13 sampling; therefore the batch is released. That's what  
14 you would do.

15 Q Okay.

16 A Uh-huh.

17 MR. ANDERTON: Let's take a brief break.

18 THE VIDEOGRAPHER: We're off the record  
19 at 4:07.

20 (A brief recess was taken.)

21 - - - - -

22 THE VIDEOGRAPHER: We're back on record.  
23 The time is 4:19.

24 - - - - -

25 CROSS EXAMINATION



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1 BY MS. DOWNIE:

2 Q Mr. Farley, my name is Ericka Downie. I'm  
3 going to ask you a few questions today, this afternoon.  
4 I was looking through the records that you brought with  
5 you today and I understood that you brought with you  
6 documents that you reviewed in preparation for your --  
7 in preparing your report as well as in preparing for  
8 your deposition today related to this litigation; is  
9 that correct?

10 A Yes.

11 Q Okay. In going through those documents I  
12 found some e-mails and some documents I wanted to  
13 question you about. Who is Hua, H-U-A?

14 A Hua.

15 Q Hua. Fair enough.

16 A Hua is Dr. Hua Zhao. He is a chemistry  
17 teacher at Savannah State University and I asked -- he's  
18 a friend, a fellow chemist and a neighbor. And I asked  
19 him to weigh a couple of tablets for me in the  
20 laboratory.

21 Q Why?

22 A I wanted to look at the various  
23 medications, the ratio of active ingredient, API, active  
24 pharmaceutical ingredient, to the total tablet weight  
25 and get those ratios.

1 Q Why was that important information for  
2 you?

3 A It was important to me because when I  
4 looked at .125 milligram strength of Digoxin, the  
5 Digitek product that is .125 strength, and then I saw  
6 that the tablet weight was 105 milligrams, I calculated  
7 that out on a -- first on a percentage basis -- I see  
8 you have the chart in front of you -- on a percentage  
9 basis and then I converted to a parts per thousand,  
10 parts of active ingredient per thousand parts total  
11 tablet weight.

12 And I'm saying this off the top of my head. I  
13 just asked Hua to do the tablet weights of the others,  
14 the Benadryl, the Advil. I did not have the tablet  
15 weight of Digitek, but I got the tablet weight from the  
16 records. And then I calculated that for the .125  
17 strength Digitek.

18 That is just over one part of active  
19 ingredient, 1.2 parts perhaps of active ingredient, to a  
20 thousand parts of total blend. And that's difficult to  
21 mix, I would believe, such a dilute mixture.

22 So he weighed a Benadryl, he weighed a  
23 Lipitor -- and that was right out of my prescription  
24 bottle, the Lipitor -- and an Advil. And I think you  
25 have the --

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1 Q And it appears -- I'm sorry -- also  
2 Diovan.

3 A Diovan.

4 Q Right. Okay. So he did these weights for  
5 you?

6 A He just did the tablet weights.

7 Q Right.

8 A The strengths are the claimed strengths on  
9 the labels.

10 Q Okay.

11 A And I just looked -- and I'm looking at  
12 the data upside down as you have it there --

13 Q Right.

14 A -- that when I looked and I said to  
15 myself, wow, this is 1.2 parts per million mixture of  
16 the active ingredient in the Digitek product at the.125  
17 milligram strength, that really has to have a lot of  
18 care taken to mix it pretty thoroughly. And while the  
19 others had -- I forget. One was well over 100 --

20 Q Well, we have one that's 56, another  
21 that's 65, another that's 99. So three of them are  
22 under 100.

23 A Under? And what's the one that's --

24 Q Then there are two that are well over 100,  
25 the Advil and the Diovan.

1           A    And while you want blend uniformity in  
2   anything you mix it's, quote, unquote, it's easier to  
3   get in the Diovan or the other ingredients and it would  
4   be tougher to get in the more dilute product.

5           Q    Did you review -- did you conduct this  
6   examination at Plaintiffs' counsel's request?

7           A    No. In fact --

8           Q    And did you actually have any Digitek  
9   tablets to weigh?

10          A    No. I got that from the batch record.

11          Q    So there weren't any Digitek tablets that  
12   were actually weighed as part of this analysis that you  
13   conducted?

14               MR. MILLER: Object to form.

15          A    There weren't.

16          Q    So, Dr. -- I'm sorry.

17          A    Dr. Hua Zhao.

18          Q    Dr. Zhao, he didn't weigh any Digitek; he  
19   weighed other medications for you.

20          A    The others that you have in the bag there.

21          Q    And you haven't reviewed any other batch  
22   records with respect to Digitek to determine anything  
23   regarding blend uniformity or content or anything of  
24   that nature for a product that was actually released and  
25   distributed on the market?

1 A Did not, only that one lot in question.

2 Q And do you -- this looks like this  
3 analysis was done on June 11th, 2010?

4 A That's probably when Hua gave me the data  
5 or sometime there and I just entered it and did my  
6 calculations on the Excel spreadsheet there.

7 Q Approximately how many hours have you  
8 spent on this litigation?

9 A On the litigation total?

10 Q Yeah.

11 A I'm pausing because I'm thinking back to  
12 the billable hours.

13 Q If you can just give me an estimate.

14 A About 175.

15 Q And are you currently engaged by any other  
16 entities or facilities with respect to consulting? Any  
17 other consulting engagements currently?

18 A I just finished one. I have another  
19 pending but not actually doing it right now.

20 Q Okay.

21 MS. DOWNIE: All right. I'm going to  
22 turn the questioning back to Mr. Anderton.

23 MR. ANDERTON: Okay. Thank you.

24 - - - - -

25 DIRECT EXAMINATION (Cont'd)

1 BY MR. ANDERTON:

2 Q Mr. Farley, I started to ask you some  
3 questions about this earlier and then I changed course  
4 and I never finished my thoughts on this issue. So I  
5 want to follow up.

6 We looked at the FDA document from the Web  
7 site which indicates the FDA's thoughts that the recall  
8 of this product is -- flows from the double thick  
9 tablets found in one lot.

10 Would it bother you -- or does it bother you  
11 to know as you form your opinion in this case that  
12 Plaintiffs have changed their theory -- we started  
13 talking about theory earlier -- and that initially they  
14 brought claims that they were taking and had taken  
15 double thick tablets and that since then they've changed  
16 their theory to now being pursuing this notion of  
17 varying degrees of active pharmaceutical ingredients,  
18 whether the tablet is double thick or not?

19 MR. MILLER: Objection. Object to form,  
20 overbroad and it's facts not in evidence.

21 Q You may answer.

22 A Well, I didn't know it. Since I didn't  
23 know it it doesn't bother me.

24 Q Hearing it now does it bother you?

25 A No. My work was look at these documents,

1 provide an evaluation. And I -- it would bother me if I  
2 thought people were dying taking medication, I mean, as  
3 a fellow human being. But speaking of the case, no.

4 Q Do you know how many lots were subject to  
5 this recall?

6 A The number 33 comes up and a number of 85  
7 comes up.

8 Q Okay. If I told you it was 152, would you  
9 have any reason to doubt that?

10 A I would not have any reason to doubt that.  
11 In fact, I would relate it to the number that you  
12 mentioned earlier.

13 Q Okay. And if I tell you that the .125 --  
14 the theoretical batch size of .125 is 4.8 million and  
15 the theoretical batch size of .25 is 4.2 million, do you  
16 have any reason to doubt those numbers?

17 A No reason to doubt them.

18 Q So if there's 152 batches that were  
19 subject to recall in this case, those numbers mean we're  
20 looking at north of 680 million tablets.

21 Does that sound about right?

22 A Quick calculation, sounds about right.

23 Q Okay. Not a single double thick tablet  
24 has been presented to Defendants in this case. Do  
25 you -- are you aware of that?

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1 A I was not aware of that.

2 Q Is that something you would have liked to  
3 have known as you formulated your opinion, as you put  
4 it, as you evaluated Digitek?

5 A It would have been helpful but not  
6 necessary. When I read those 483s and I saw the  
7 observations on the 483s and I read the warning letters  
8 to -- now to answer with that knowledge after reading  
9 that to answer your question, oh, it wouldn't matter.

10 Q The 483s would do nothing but prompt you  
11 to look further, right?

12 A It would prompt me to look further because  
13 I see violations and I want to know why don't they  
14 correct them, are they going to correct them, which is  
15 what FDA wants to know.

16 Q Okay. And they would prompt you to -- if  
17 you're evaluating Digitek and if you're doing it  
18 properly, you'd take the information you learned in the  
19 483 and you'd evaluate information reflecting the  
20 manufacturer of Digitek, right?

21 A Yes, but I'm taking the FDA's word for  
22 what they put in the 483. I'm not --

23 Q You still have to connect --

24 MR. MILLER: Hang on. He's answering.

25 You're cutting him off.



1 Q Go ahead and answer.

2 A I'm not looking for supplemental  
3 information because I doubt the FDA's content of the 483  
4 or the warning letter. But any supplemental information  
5 is always helpful.

6 Q Well, you still have to connect the  
7 information on the FDA's documents to Digitek, right?

8 A Oh, yes. In some cases they mention it  
9 and other cases they mention other products.

10 Q And in the cases where they don't mention  
11 Digitek, as you said earlier, you have to connect that  
12 specific citation to Digitek --

13 MR. MILLER: Object to form.

14 Q -- somehow.

15 MR. MILLER: Misstates previous  
16 testimony.

17 A I'm looking to evaluate the whole firm and  
18 Digitek, but I'm not looking to say how can I get this  
19 to make it look bad for Digitek. No, I'm not. Maybe  
20 I'm not getting the question right.

21 Q Yeah. Let me try to say it differently.  
22 Let's separate your evaluation of the firm from your  
23 evaluation of Digitek. All right?

24 MR. MILLER: Object to form.

25 Q So I don't want to hear in my response to

1 this question about your evaluation of the firm. As  
2 you're evaluating Digitek and forming an opinion about  
3 Digitek, if you find a reference on a FDA form to a --  
4 what the inspector believes is a GMP deficiency, in  
5 order to evaluate Digitek, as you testified earlier, you  
6 have to go look for information about Digitek, right?

7 MR. MILLER: Object to form.

8 A Yes, but I would also look for more  
9 information about how they're making other things if  
10 it's in the same plant by the same people. I would do  
11 what you say first, but not only, because although you  
12 said to me separate Digitek from the firm, I can try to  
13 do it but there's overlap. There's overlap.

14 It's the firm that makes the Digitek. It's  
15 the same firm that made these products that's making the  
16 Digitek. So I know you said to me separate it, but I  
17 can't completely separate it.

18 Q Is it your opinion that if a firm makes  
19 one product defectively they make all products  
20 defectively?

21 A No. It's my opinion that there is a  
22 possibility that some other products are being made  
23 defectively.

24 Q But you can't confirm unless you look at  
25 records, right?

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1 A That's right.

2 Q You know about batch yields, right?

3 A Yes.

4 Q Are you -- a theoretical yield is the  
5 number of tablets that should be produced in a typical  
6 batch if tablets are manufactured within specification,  
7 correct?

8 A Yes.

9 Q If batches contained double thick tablets,  
10 that would potentially impact the yield of the batch,  
11 right?

12 A Of the number of tablets, yes.

13 Q Something you could examine as part of  
14 your evaluation of Digitek?

15 A Yes.

16 Q You didn't do that, did you?

17 A For the number of tablets, 15 out of 4.8  
18 million, the yield would not have given me an indication  
19 either way.

20 Q It wouldn't be because 15 or even 20 is in  
21 fact I think the real number, 20 out of 4.8 million  
22 would not have affected the yield.

23 A The yield as in the specifications. I  
24 forget the number offhand, but if it's so many kilograms  
25 put in and 98 to 102 percent and it came out, you

1 wouldn't see it by looking in that area.

2 Q Okay. But you didn't look at any yield  
3 for any batches other than the double thick batch?

4 A And that was in reviewing the whole batch  
5 record I saw you go through.

6 Q So as I understand that comment, you saw  
7 the yield but not because you were looking for the  
8 yield. You just were reviewing the batch record and it  
9 was in there.

10 A It's one of those things where you're  
11 looking at an aspect of something and you want to look  
12 at other parameters. Which parameters do you look at  
13 that will give you information that will help you  
14 explain this situation? And I don't think that would  
15 give me any information.

16 Q Are you familiar with Quantic Regulatory  
17 Services, Quantic?

18 A Am I familiar with it. I've done work for  
19 them.

20 Q You have done work for them?

21 A Sure.

22 Q Are you aware that they -- at the request  
23 of the FDA that Actavis hired Quantic to undertake a  
24 review of various batch records and documents?

25 A Quantic is good on that. I've done batch

1 reviews for them on other projects, other clients.

2 Q You trust their results?

3 A I trust Quantic's results.

4 THE VIDEOGRAPHER: I have to change tape  
5 now.

6 MR. ANDERTON: Okay.

7 THE VIDEOGRAPHER: Off at 4:35. One  
8 moment, please.

9 (Off the record.)

10 THE VIDEOGRAPHER: Okay. This is the  
11 beginning of Tape No. 7. It is 4:36 p.m.

12 BY MR. ANDERTON:

13 Q Mr. Farley, before we changed tapes I  
14 asked you a question about Quantic Regulatory Services.  
15 You indicated that -- there were several questions. You  
16 indicated you're familiar with them, you've worked with  
17 them and for them and that you trust them.

18 Is that a fair characterization?

19 A Yes, to all.

20 Q Okay. But you didn't answer the question  
21 I asked you originally which was, were you aware that  
22 Actavis hired Quantic to undertake an audit review of  
23 batch records at the request of the FDA in 2007?

24 A Not the way you say it. I saw Claudio  
25 Pincus' name and Owen Richards' name. And Claudio

1 Pincus and Owen Richards are Quantic. They own it. And  
2 so I knew they were involved because I saw their name on  
3 correspondence or they were cc'd on some e-mail. So I  
4 realized that. And I also saw PAREXEL, which is a  
5 competing firm. So that's how I knew.

6 Q Did you ask for any documents relating to  
7 Quantic's involvement?

8 A No, I did not.

9 Q You trust them. You knew they were  
10 involved. You didn't ask to see what they had done or  
11 what the results were?

12 A I didn't need to. If Claudio has a team  
13 in there doing a job, they're doing a good job. I did  
14 that type of work for him on various projects.

15 Q I'm not asking if you asked to see  
16 Quantic's documents because I'm asking you to second  
17 guess their results. I'm asking you whether you thought  
18 that was potentially relevant to your evaluation of the  
19 firm.

20 If Quantic did a good job, as you've now said  
21 multiple times --

22 A Yes.

23 Q -- wouldn't you want to see their outcome  
24 as part of your evaluation of the company?

25 MR. MILLER: Object to form.

1           A    I want to see the immediate FDA inspection  
2   that follows Claudio's implementation of the results to  
3   verify that what he did, and which I have explicit  
4   trust, has been put to use satisfactory.

5           So I don't need to see what Claudio's doing --  
6   or I should say Quantic was doing. I want to see the  
7   FDA inspection, because they're the ones that are going  
8   to say you can now market it or you can't market it. So  
9   that's why I didn't ask to see it. And this moment I  
10   still don't care to see it.

11          Q    What's a compliance hold? Do you know?

12          A    You're holding something until something  
13   else is done and then you will release it when that  
14   something else is done. That's obviously not the FDA  
15   definition.

16          Q    What's the FDA definition of a compliance  
17   hold?

18          A    I gave you mine because I was vague on  
19   their words. That's why I gave you mine.

20          Q    Okay. Let me ask it a different way.  
21   When a company has been issued a warning letter -- and  
22   I'll characterize that as being under or subject to a  
23   warning letter -- is the company -- is the FDA going to  
24   grant new product approvals while that is the case?

25          A    In a warning letter?

1 Q Yes.

2 A That would depend on the content of the  
3 warning letter, the scope of the warning letter and what  
4 else was needed. If it all centered in one location --  
5 I mean same company, one location, and there was never  
6 any problem with another location of the same company  
7 and the warning letter applied here, they may let them  
8 produce here.

9 Q At the other location.

10 A Yes.

11 Q What if it's all one location?

12 A Here again we get into that it is quite  
13 likely not, but in certain instances of a product that  
14 is needed in the market, when you have someone who is  
15 primary supplier and the shortage of that product on the  
16 market would be harmful to people who need the  
17 medication, they will -- I don't know how to put -- work  
18 with the company, but put that in quotes, work with the  
19 company in trying to help them get the product to  
20 market. So it will be a warning letter --

21 Q Are you talking about a product that's  
22 already been approved?

23 A Yes.

24 Q Okay. I asked you about new approvals.

25 A New approvals.



1 Q Yes. Will the FDA grant new product  
2 approvals while a company is under a warning letter?

3 A Quite likely not but in theory they could.

4 Q In your experience have you ever seen that  
5 happen?

6 A No.

7 Q You were -- were you told by Plaintiffs'  
8 lawyers in this -- as you were preparing your report for  
9 this litigation that after the 2007 inspection that we  
10 talked about earlier eight to ten new product approvals  
11 were granted by the FDA to Actavis Totowa within two  
12 months after that?

13 A No, I don't recall that.

14 Q Were you told by the plaintiffs' lawyers  
15 that the outcome of that inspection is that the warning  
16 letter that had been in effect since early 2007 was  
17 lifted?

18 A I wasn't told. I have information that  
19 I've been reviewing.

20 Q And you saw the outcome of that 2007  
21 inspection was VAI, correct --

22 A Yes.

23 Q -- voluntary actions indicated?

24 A Yes.

25 Q So if Quantic did a review of Digitek

1 batch records as part of a project for which they were  
2 hired by Actavis in 2007 and that review included  
3 recalled batches, that's of no interest to you in  
4 evaluating Digitek?

5 A It's of interest to me, but what is more  
6 interest is what the FDA says. Quantic is coming in to  
7 fix it and if someone comes in and says, hey, that's  
8 great, they can market it, I want to see what the FDA  
9 says, because the FDA is the regulatory body. Quantic  
10 isn't.

11 Q Quantic is not coming in to fix it.  
12 They're coming in to review what had already been  
13 released.

14 A They do both and I wasn't sure what they  
15 did here.

16 Q Well, what they did here was review what  
17 had already been released. So let me start that over a  
18 little bit.

19 If Quantic came in and reviewed batch records  
20 for Digitek that had been released to market to  
21 determine compliance, is that something you'd want to  
22 see as you evaluate Digitek?

23 MR. MILLER: Objection, asked and  
24 answered.

25 A It would be helpful to see, but I want to

1 see what the FDA says. We keep coming back to this.

2 Q But Quantic was hired at the request of  
3 the FDA and the results were submitted to the FDA.

4 Would that be of significance to you?

5 MR. MILLER: Objection, asked and  
6 answered.

7 MR. ANDERTON: It hasn't been asked and  
8 answered, Pete. Not close to asked and answered.

9 A I thought it was. So I guess I better --  
10 let me think. It would be of interest to me, but it  
11 wouldn't be absolutely necessary. I read a series of  
12 483s and a couple of warning letters and I have a very  
13 low opinion of the capabilities of the company.

14 Q Based on that review of those 483s --

15 A Those several 483s --

16 Q -- and the warning letter.

17 A -- and the various EIRs. And if a company  
18 like Quantic is coming in to review the batch records, I  
19 say fine. And if you say what's the company look like,  
20 let me see the latest thing from FDA that says they're  
21 good again.

22 But -- so that's why I don't think that I miss  
23 what they -- I know they're good. I know what they do.  
24 And they do in some cases help prepare, actually put  
25 people in position.

1           And -- but I didn't have to see that. It  
2     won't change my judgment of what was and what needs to  
3     be to have a quality product on the market.

4           Q     Let's turn to your report. Again my copy  
5     has disappeared. Will you turn to page 17, Mr. Farley?

6           A     I am at 17.

7           Q     What is the purpose of the comments  
8     section of this report?

9           A     My comments -- I didn't know who all was  
10    going to read this, how familiar the people would be  
11    with the pharmaceutical industry.

12           And in this regard I do remember I asked Peter  
13    Miller, I said, in doing my report I don't know the  
14    whole readership of this and I would like to put in a  
15    comments section that's going to maybe make it a little  
16    more worthy, but I feel it will explain things.

17           And the reply was something to the effect of,  
18    whatever tells the story when in doubt. So I requested  
19    the okay to put a comments section in for the reason I  
20    just mentioned.

21           Q     Okay. So those aren't part of your  
22    official expert opinions in this case. They're  
23    background information that you feel helps tell the  
24    story and allows the reader who might not have FDA  
25    experience to have a better understanding of the

1 opinions you've offered which are in the conclusion  
2 section.

3 MR. MILLER: Object to form, misstates  
4 previous testimony.

5 A I got lost somewhere in that question.

6 MR. ANDERTON: Will you please read that  
7 back and read it relatively slow so that I can  
8 understand it as well. I need it slow.

9 (The record was read back as requested.)

10 A There are facts and opinions in here. I  
11 do some quotes, which, of course, are facts. And then  
12 I'm looking to see where -- well, just statements.  
13 Recalls are actions taken by a firm. I'm reading D.  
14 What I am doing is exploring that are these my opinions.  
15 I'm looking to see if I have opinions in here.

16 Q So I think your testimony is that you do  
17 have opinions in your comments section.

18 A I'm looking here where I have that total  
19 failure thing again. When I say to have a total failure  
20 such as this indicates there's no product of this  
21 company at that location that can be relied on, that's  
22 my opinion. I'm sure it's shared by many, many, many  
23 people that I work with. But you could classify that as  
24 an opinion.

25 Q Okay. So let's work our way through these

1 then. That Paragraph A on page 17, it's accurate to say  
2 that that's based entirely on that -- the notes of that  
3 close-out meeting, correct?

4 MR. MILLER: Objection, asked and  
5 answered.

6 A Based on that three- or four-page --

7 Q Yes.

8 A -- correspondence that we saw? I saw  
9 somewhere else somewhere Robert Wessman and agreement.  
10 Other than that I just can't remember it now, so --

11 Q Well, you've indicated here that you're  
12 quoting Plaintiffs' Exhibit 106.

13 A I am.

14 Q And you're not referring to any other  
15 document and you're using quotes.

16 A I did in there, right. Yes. Everything  
17 you said is correct.

18 Q So this paragraph refers exclusively to  
19 Plaintiffs' Exhibit 106?

20 A But I saw Wessman's name somewhere else  
21 and I'm just not clicking whether I relate it to this.  
22 But predominantly that three- or four-page  
23 correspondence, unsigned and undated on Actavis  
24 letterhead.

25 Q Well, how can -- Mr. Farley, let's not

1 throw common sense out the window. Okay?

2 A Right.

3 MR. MILLER: Object to form.

4 Q In the first sentence here you refer  
5 exclusively to Plaintiffs' Exhibit 106. And the rest of  
6 the text until your opinion is in quotes.

7 MR. MILLER: Is that a question?

8 A What is -- I don't understand the  
9 question.

10 Q So how can it not be true that that  
11 paragraph and that opinion is based entirely instead of  
12 just predominantly on Plaintiffs' Exhibit 106 when you  
13 refer to it and then quote exclusively from it?

14 A It quite likely is exclusively from it,  
15 but I remember reading the name Wessman somewhere else.  
16 And I may have incorporated some of that in there, if in  
17 fact I'm correct.

18 Q So you may have incorporated some of that  
19 in there even though you refer to a document and then go  
20 on to quote from it twice. So the reader is supposed to  
21 understand that the next comment actually incorporate --  
22 and then in the next sentence you go back and quote from  
23 it again, to have a total failure.

24 Do you see that?

25 A Yes.

1 Q Okay. That's another quote from  
2 Plaintiffs' Exhibit 106.

3 A From Plaintiffs' 106.

4 Q So the reader is supposed to be able to  
5 understand that you've actually, perhaps implicitly, but  
6 without giving anything that would indicate such worked  
7 information from another document into that comment?

8 MR. MILLER: Object to form.

9 A I did not work information from another  
10 document into that.

11 Q Okay. Then my question stands. Is it  
12 accurate to say that the comment in Paragraph A is based  
13 entirely on Plaintiffs' Exhibit 106?

14 A To the best of my knowledge, yes.

15 Q Okay. Now, this total failure comment  
16 that is in the Plaintiffs' Exhibit 106 which we talked  
17 about earlier, it doesn't appear in an EIR, does it?

18 A It appears in -- well, the Actavis  
19 document is quoting from what, the lady's name, Erin,  
20 the inspector, either wrote or said.

21 Q My question is, does it appear in an EIR?

22 A I don't remember if it's written or said.

23 Q Wouldn't you have cited and quoted that if  
24 it appeared in an EIR? I mean, that's a little more  
25 official than scribed notes, right?



1 MR. MILLER: Object to form.

2 A I may or may not have.

3 Q Total failure would be the opinion of the  
4 investigator, right?

5 A Since Actavis -- go ahead.

6 Q Total failure would be the opinion of the  
7 investigator, right?

8 A Yes. And I think I read that somewhere.

9 Q You did, in Plaintiffs' Exhibit 106 to the  
10 extent it's accurate.

11 A I believe that whoever wrote that was  
12 referring to what Erin, the inspector, said to him or  
13 her.

14 Q Okay. But I'm now -- I'm simply trying to  
15 ask you, Mr. Farley, and if you just pay very close  
16 attention --

17 A I'm trying.

18 Q -- I'm trying to ask you whether it  
19 appears in another document. That's not that difficult  
20 a question, yet you're so intent on not conceding this  
21 that you're just ignoring my question and answering  
22 whatever question you want.

23 A Can I see Plaintiffs' 106?

24 Q Can you see it?

25 A Yeah.

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1 Q You absolutely may. You absolutely may.

2 A I can't find Plaintiffs' 106. I've got a  
3 big pile here. Let me look through my pile. 106,  
4 page 1, whoever the author was is referring to Erin  
5 McCaffery and seems to be quoting -- she puts total  
6 failure in quotes -- leading me to believe that Erin  
7 McCaffery said or wrote it.

8 Q Now, my question is, that total failure  
9 comment doesn't appear in an EIR, does it?

10 A I don't remember if it's in an EIR.

11 Q Well, the document will speak for itself.

12 A Yes.

13 Q But it either does or it doesn't, right?

14 A It either does or doesn't.

15 Q And that would be the opinion of the  
16 investigator, right?

17 A She would be reflecting an opinion based  
18 on facts that she observed.

19 Q So it wouldn't belong in an EIR if it's  
20 there, right?

21 A They're not supposed to put opinions.  
22 You're not supposed to put opinions on 483s. You're  
23 supposed to put facts on 483s and you're only supposed  
24 to put facts on EIRs also.

25 Q So it doesn't belong in either an EIR or a

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1 483.

2 MR. MILLER: Object to form.

3 A That is correct.

4 Q And in fact, it doesn't appear in either  
5 the EIR or the 483, does it?

6 A I don't -- apparently Erin McCaffery  
7 either wrote it or said it, because she's being quoted.  
8 That's why I put the single quotes in there.

9 Q Okay. In Comment A you refer to products  
10 with no impurity profile. Do you see that?

11 A 48 products with no impurity profile.

12 Q Was Digitek one of those products?

13 A Don't know.

14 Q You didn't review any batch records to  
15 find out, did you?

16 A Did not have to.

17 Q You didn't review any batch records to  
18 find out, did you?

19 A Correct.

20 MR. MILLER: Objection.

21 Q Paragraph B --

22 A Yes.

23 Q -- you quote from a complaint for  
24 permanent injunction and then you offer a comment. Now,  
25 you authored an article with lawyers. I assume you've

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1 been around enough to know, and you worked for FDA for  
2 eight years, you know a complaint is nothing but  
3 allegations, right?

4 MR. MILLER: Object to form, calls for a  
5 legal conclusion.

6 A I'm thinking of that. The way you have it  
7 worded I'd say it's an allegation.

8 Q Allegations are -- statements in a  
9 complaint are allegations, right?

10 A Yes.

11 Q Untested, unproved.

12 MR. MILLER: Object to form.

13 A Yes.

14 Q Your comment in Paragraph B, this leads  
15 any responsible person to ask why didn't they fix what  
16 was broken.

17 A Yes.

18 Q Did one of Plaintiffs' lawyers suggest  
19 that things were broken at Actavis to you?

20 A No.

21 Q Did you ever talk to a gentleman named Ed  
22 Blizzard?

23 A No. I've read that name in depositions.

24 Q Okay.

25 A He's an attorney?

1 Q He is an attorney.

2 A I've never spoken to or met the gentleman.

3 Q Okay. We spent a lot of time going  
4 through the EIR for the 2007 inspection. Do you  
5 remember that?

6 A Yes.

7 Q Fifteen observations. Every one Actavis  
8 proposed and implemented corrective actions in response  
9 to every one. Do you remember that?

10 A I don't remember implementing them. What  
11 I saw was, here's what we're going to do, here's what  
12 we're going to do here, here's what we're going to do,  
13 we hire this many people.

14 And then I was trying to say time will tell if  
15 it works out if they really do it. But at that instant  
16 in time that's what they proposed.

17 Q Okay. Mr. Farley --

18 A We had a difference there.

19 Q Mr. Farley, it isn't what they proposed;  
20 it's what they did. There's a difference between doing  
21 and your notion of time will tell whether it is the  
22 absolute effective solution.

23 You understand that, right?

24 MR. MILLER: Object to form,  
25 argumentative.

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1 A State your two points, now.

2 Q You understand that, right, that there's a  
3 difference --

4 A Yes, I do.

5 Q Okay. And if we have to go back through  
6 that again and convene for another day of deposition,  
7 I'm happy to do that.

8 A Fine.

9 Q The record will show what it shows.

10 A Yes.

11 Q But in fact, the EIR shows 15  
12 observations, 15 sets of corrective actions actually  
13 taken by Actavis, doesn't it?

14 A Taken, started at that time.

15 Q Yes.

16 A Yes.

17 Q None of them indicated by -- nowhere does  
18 the FDA indicate that additional corrective actions are  
19 necessary.

20 A Not if they work out.

21 Q Well, but the FDA is saying no corrective  
22 actions are necessary. You gave that testimony in  
23 response to all 15. You're not going to go back on  
24 that, are you?

25 MR. MILLER: Object to form.

1 A I'm not.

2 MR. MILLER: Misstates previous  
3 testimony.

4 A But the FDA is also saying back at their  
5 district office, let's get the calendar and look when  
6 we're going to inspect them to make sure those  
7 corrections work out.

8 Q Okay.

9 A That's the point that I'm trying to make.

10 Q And I'm not suggesting that they are  
11 absolved of compliance on all those issues forever.

12 A Yes.

13 Q I merely want to explore the notion of  
14 whether corrective actions were taken.

15 A They were.

16 Q Absolutely were.

17 A We agreed on that step by step, every one.

18 Q All the way through.

19 A Sure.

20 Q Go to Paragraph C.

21 A I'm there.

22 Q It's not true that companies hire third  
23 parties only when they can't achieve compliance by  
24 themselves, is it?

25 A You say it's not true?

1 Q Yeah.

2 A Correct. It is not true. They hire third  
3 parties to help them out whenever they feel they need  
4 them, not necessarily when they have a problem.

5 Q Okay. And sometimes they hire them just  
6 because maybe they want to expedite something and they  
7 don't necessarily have the resources themselves to do it  
8 and they want some assistance making sure something  
9 happens within a time frame that they need to  
10 accomplish, correct?

11 A Yes.

12 Q Have you ever been hired for that purpose?

13 A Yes.

14 Q How many times?

15 A A few times every year for a variety of  
16 things, reviewing internal documents, evaluating a  
17 contract manufacturer or contract packager. It varies  
18 as to what they need you for.

19 Q Okay. And you also can hire a GMP expert  
20 to evaluate your methods and facilities and controls  
21 just because you want to conduct some sort of  
22 evaluation, correct?

23 A Yes.

24 Q And that happens?

25 A Yes.



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1 Q So it's not true that that happens only in  
2 the context of a consent decree.

3 A Correct.

4 Q You're aware that all of the other  
5 products made by Actavis Totowa other than Digitek were  
6 recalled at some point during 2008, right?

7 A Yes.

8 Q Are you aware that was not a consumer  
9 level recall?

10 A Yes.

11 Q Patients were instructed to continue  
12 taking those products?

13 A Yes.

14 Q By the FDA.

15 A Yes.

16 Q Why would the FDA do that?

17 A Were permitted to by the FDA, I would say.

18 Q Well --

19 A If you want to say instructed, I'm saying  
20 permitted.

21 Q Press releases announcing recalls are  
22 submitted and approved by the FDA, correct?

23 A You're not talking about these unsigned  
24 things that you saw on the Web that you showed me?

25 Q No. I'm talking about the official press

1 release --

2 A Official press release?

3 Q -- where a recall is announced.

4 A Yes.

5 Q Submitted to and approved by the FDA,  
6 right?

7 A Yes.

8 Q So the press release -- the press release  
9 that announced the recall of the products other than  
10 Digitek was submitted to and approved by the FDA?

11 A Yes.

12 Q Had to be.

13 A Oh, yes.

14 Q So it told consumers to continue taking  
15 all those products submitted to and approved by the FDA,  
16 right?

17 A Yes. That took a minute, but then it  
18 kicked in to my memory.

19 Q Okay. Let's go back to this comment  
20 about -- you keep wanting to say that sometimes the FDA  
21 will let a product go to market if it's necessary.

22 What's the basis for that statement?

23 A Let's say that a particular firm, Firm A,  
24 makes a product and it has 80 percent of the market of  
25 that product. But Firm A now encounters a problem with

1 that.

2 But if Firm A were to be shut down there would  
3 be patients who couldn't get the product because the  
4 only other firm that makes it doesn't make enough of it  
5 and can't get gear's up to do it.

6 So the FDA will then come. And remember I  
7 said put work with in quotes. They'll work with them in  
8 giving them more guidance in how can we approve things  
9 to get them out to the people who need it. That's what  
10 I was referring to. They're rare cases indeed, but they  
11 do happen.

12 Q Well -- and ultimately the only thing that  
13 really matters is GMP compliance, right?

14 A That's right.

15 Q So it doesn't matter whether the product  
16 is important or not. If you don't have GMP compliance  
17 it's not going to market.

18 A That's correct.

19 Q Now, you keep -- or you've referred  
20 several times and I believe earlier you actually said an  
21 observation you use interchangeably with a violation on  
22 a 483.

23 A In conversation I use it interchangeably.

24 Q Okay. I guess that's a qualification on  
25 your earlier testimony then. So I need to make clear.

1 And we talked about this a little bit earlier.

2 An observation on a 483 is not -- is not even  
3 intended to reflect an actual violation. It's just the  
4 observation of the inspector about some condition that  
5 they want to see changed.

6 A That they want to see changed because it's  
7 violative.

8 Q Well, will you look at your report on page  
9 18, Mr. Farley.

10 A Page 18?

11 Q Yeah.

12 A I'm there.

13 Q And you, in Paragraph E on the Fact versus  
14 Opinion --

15 A Yes.

16 Q -- you quote the Investigations Operations  
17 Manual, Section 5.2.3.3 as reading, Do not -- quote, Do  
18 not report opinions, conclusions or characterize  
19 conditions as violative. The determination of whether  
20 any condition is violative is an agency decision made  
21 after considering all circumstances, facts and evidence.

22 Do you see that?

23 A I see it.

24 Q Did I read that correctly?

25 A You read it correctly.

1 Q I have the section here as an exhibit, but  
2 do you believe you accurately quoted that --

3 A I believe I accurately quoted that.

4 Q -- operations manual? So the operations  
5 manual tells inspectors, whatever you write don't  
6 indicate it as a violation, we'll do that after the --  
7 somewhere down the line, right?

8 A Say that again.

9 Q The operations manual is saying here to  
10 inspectors, whatever you write don't indicate it as a  
11 violation, we'll figure out whether it's a violation  
12 later.

13 A I have to explain what that means.

14 Q What what means?

15 A What that means, they determine as  
16 violative.

17 Q It means that they haven't made a  
18 determination as to whether it's a violation.

19 MR. MILLER: Are you testifying for him?

20 A It's, it's the way the system is set up.  
21 The inspectors come back from an inspection along with  
22 the scientists. The scientists go to the lab visiting  
23 the inspectors periodically to help with the report.  
24 The compliance division, which is -- exists as  
25 another division within the district, their

1 responsibility is to determine the classification. Is  
2 it NAI, no action indicated; is it VAI; is it OAI,  
3 official action indicated? It's their area.

4 So in not treading into their work area it's  
5 essentially, you do the inspection, you make your  
6 observations. They don't doubt them. They just say,  
7 make your observations. But then it comes to this area  
8 to look at it and determine whether it's a NAI, VAI or  
9 OAI.

10 Q This doesn't say anything about NAI, VAI  
11 or OAI, does it?

12 A But the violative status that -- it's just  
13 a matter of responsibilities. We will over here  
14 determine if it's violative. You wrote it, you know it,  
15 anybody that reads it knows it, but over here we are the  
16 ones who officially make it violative.

17 Q And until you get over here where you make  
18 that official determination it's not violative.

19 A And over here is right across the hall.  
20 It would be like right over there.

21 Q I understand, but that happens after the  
22 483 is issued.

23 A Legally that's the process. In the  
24 regulatory system that's the process.

25 Q So yes. The answer is yes.

1 A Yes.

2 Q It happens after the 483 is issued.

3 A Yes. Everybody knows it's going to be,  
4 but it isn't official until it goes across the hall and  
5 they do it.

6 Q Paragraph F.

7 A Yes.

8 Q When you use the term systemic -- well,  
9 when you say in the last sentence there all products,  
10 including Digitek, were adulterated -- you see that --

11 A Yes.

12 Q -- did you -- you didn't review any  
13 Digitek batch records to reach that conclusion.

14 A I reviewed one Digitek batch record, but  
15 that did not come into this conclusion.

16 Q Well, this conclusion flows exclusively  
17 from FDA documents.

18 A Yes. In fact, it's not in the conclusion  
19 section. It's in the comments section.

20 Q This comment flows exclusively from your  
21 review of FDA documents. You took the FDA at their  
22 word.

23 A Yes.

24 Q You didn't do anything to follow up and  
25 specifically determine whether Digitek was adulterated.

1           A    Looking at failure to -- when you're not  
2   manufacturing in compliance with GMPs, by definition in  
3   the Act it's adulterated.

4           Q    You didn't do anything to follow up and  
5   find out whether Digitek other than Batch 70924 --

6                   MR. MILLER: Object to form.

7           Q    -- had not been -- had been manufactured  
8   not in compliance with GMPs.

9                   MR. MILLER: Object to form, misstates  
10   previous testimony.

11           A    I didn't do anything beyond all the other  
12   483 -- reading the 483s and -- well, I was looking for  
13   everything in there, not just for Digitek.

14           Q    I understand that. But we talked earlier  
15   about what you do when you find that situation and you  
16   want to associate it with a specific product, you go  
17   look at the records for that product. You didn't do  
18   that.

19           A    The way you have worded the question, no,  
20   I didn't do that. I looked at the batch record for that  
21   one lot.

22           Q    Blend Uniformity, Paragraph G.

23           A    Yes.

24           Q    You talk about the products that were  
25   temporarily discontinued due to blend uniformity and/or



1 content uniformity issues.

2 Do you see that?

3 A I see it.

4 Q Was Digitek one of those products?

5 A I just don't recall offhand. Perhaps I  
6 should, but I just don't recall offhand.

7 Q Okay. Well, don't you think you would  
8 have said that if it was in your comment?

9 A I may or may not.

10 Q Did you see any Digitek batch records that  
11 indicated out of specification results for content  
12 uniformity for Digitek?

13 A I don't believe I saw any of them, but I  
14 do believe I saw someone questioning blend uniformity.  
15 And it was correspondence between two individuals, but  
16 with 93 documents I'm at a loss to tell you.

17 Q So the answer to my content uniformity  
18 question is, no, you didn't see any documents  
19 questioning the -- or indicating out of specification  
20 results for content uniformity for Digitek.

21 A Not indicating. There was someone  
22 questioned it.

23 Q Content uniformity or blend uniformity?

24 A Content. There was content uniformity and  
25 blend uniformity somewhere in all those documents. But

1 I -- your question was did I see any. No.

2 Q Blend uniformity actually isn't required  
3 for all products in the market, is it?

4 A Could you explain that answer, blend  
5 uniformity determination?

6 Q What?

7 A Blend uniformity determination -- blend  
8 uniformity is required.

9 Q Blend uniformity testing isn't required  
10 for all products in the market, is it?

11 A You would not need it for a liquid  
12 injectable. Your sampling procedure would take care of  
13 that.

14 Q The FDA will allow companies to not test  
15 for blend uniformity in certain circumstances; isn't  
16 that correct?

17 A They won't allow them to not test for it,  
18 but your question is blend uniformity is the way I heard  
19 it.

20 Q I said -- I revised my question,  
21 Mr. Farley, to ask --

22 A Oh. You revised the question.

23 Q -- blend uniformity testing is not  
24 required for all products in this market, correct?

25 A Correct.

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1 Q Including things other than liquids,  
2 correct?

3 A Correct.

4 Q So there are solid oral dose tablets that  
5 are dry blends --

6 A Yes.

7 Q -- where the FDA allows companies to not  
8 test for blend uniformity, correct?

9 A Yes.

10 Q And will you look at Defendants'  
11 Exhibit 58? It is the 2008 483.

12 A I'm looking through. Didn't get it yet.

13 Q Perhaps Mr. Miller can lend some  
14 assistance.

15 MR. MILLER: You're getting hotter.

16 THE WITNESS: What's the exhibit number?

17 MR. MILLER: It's in that pile right  
18 here.

19 THE WITNESS: Which exhibit number is it?

20 MR. ANDERTON: 58.

21 MR. MILLER: No, the next one. It should  
22 be this one here. Is that 2008?

23 THE WITNESS: May of 2008, Erin  
24 McCaffery?

25 MR. ANDERTON: Yes.

1 THE WITNESS: I've got it.

2 BY MR. ANDERTON:

3 Q Turn to page -- well, I can't read the  
4 number myself. Let's call it 6. And the number down in  
5 the bottom right corner should be 28230.

6 Do you see that? It's cut off. The zero is  
7 cut off.

8 A Yes. The zero is cut off. It contains  
9 primarily Observation 4 --

10 Q Correct.

11 A -- and part of Observation 3.

12 Q Correct.

13 A I've got it.

14 Q Do you see Observation 4a refers to blend  
15 uniformity and particularly Digitek?

16 A Yes.

17 Q And I'm going to read that out loud. It  
18 says, Although three out of specification results -- and  
19 I'm going to skip the batch numbers, but -- Although  
20 three out of specification results were obtained for  
21 blend uniformity at the right top sample location for  
22 Digoxin tablets .125 milligrams -- and then it has the  
23 lots which I'm skipping -- on February 20, March 14 --  
24 February 20, 2007, March 14, 2007, and September 29,  
25 2007, no manufacturing investigations were conducted.

1 Did I read that correctly?

2 A Yes.

3 Q So the issue the FDA has here is not that  
4 there were out of specification results for blend  
5 uniformity, it's that there were no manufacturing  
6 investigations conducted.

7 MR. MILLER: Object to form. The  
8 document speaks for itself.

9 A It says three out of specification -- the  
10 very first line.

11 Q That's what happened. But the reason the  
12 FDA cites this fact, or these facts, is not because  
13 there happen to be three out of specification results.  
14 It's because they didn't conduct manufacturing  
15 investigations.

16 MR. MILLER: Object to form.

17 A The way this is written they didn't  
18 perform under the Corrective Action/Preventive Action  
19 program and investigate these results as they should  
20 have.

21 Q Right. So the problem, if you want to  
22 call it a problem, that resulted in this observation is  
23 not the mere fact that there were out of specification  
24 results, correct?

25 MR. MILLER: Object to form. The

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1 document speaks for itself.

2 A It says although they were obtained you  
3 didn't look at them.

4 Q Okay. So the FDA is not taking any issue  
5 with -- I'm trying to establish something, Mr. Farley.  
6 And you're an expert in this field. You counsel clients  
7 on reading these documents.

8 A Yes.

9 Q And you charge them a nice handsome fee to  
10 do that.

11 A Comfortable.

12 Q The issue that resulted in this  
13 observation is not the mere fact that there was an out  
14 of specification result three times in blending Digoxin,  
15 correct?

16 A Yes, yes.

17 Q All right. And this next sentence,  
18 Additional samples were used to retest the blend and  
19 were reported.

20 Do you know whether that's called for by the  
21 relevant SOP?

22 A I would think it would have to be where in  
23 the blend you were doing it, what time of the blend you  
24 were doing it. If you were nearly ready to take the  
25 blend and press out the tablets that's one thing.

1           If it's an intermediate sample, like just say  
2   a 30-minute mix, take one sample after 15 minutes and  
3   you should be in this range, then you'd have to write  
4   your specifications, your SOPs in accordance with that  
5   part of the process.

6           Q   Mr. Farley, please --

7           A   I'm trying.

8           Q   Do you know whether the SOP for blend  
9   uniformity testing allows retesting of sample -- of  
10   extra samples taken?

11          A   I do not know what their SOP says.

12          Q   Did you review their SOP?

13          A   I do not remember seeing it.

14          Q   Did you see any SOPs from Actavis?

15          A   I don't -- if I did it's only a few, but I  
16   don't remember any.

17          Q   Okay. So you rendered an expert opinion  
18   about the GMP compliance status of Actavis and didn't  
19   review a single SOP.

20          A   To my knowledge I didn't review the SOPs.

21          Q   Didn't ask for them either.

22          A   I relied on what the FDA said. The FDA  
23   said you're not in compliance with your SOPs, the ones  
24   you have.

25          Q   How was Digitek adulterated?

1           A    By not being manufactured in accordance  
2   with GMPs.

3           Q    Which GMPs?

4           A    Which?  21 CFR 211.

5           Q    All of them.

6           A    No.  That's the set.

7           Q    Which of those was Digitek not  
8   manufactured in compliance with?

9                   MR. MILLER:  Take your time.  If you need  
10   to go through all the documents we'll get all the  
11   documents.

12          Q    Absolutely right.

13          A    This is --

14                   MR. MILLER:  If you need help with the  
15   documents, like he just said, I'll help with the  
16   documents.  We'll get them all out and you can go  
17   right down the list.

18          A    I mean, I know I can come up with the  
19   answer.  I'm just trying to think and give you the  
20   answer of the correct one, of course.

21                   MR. MILLER:  Well, it's not a memory  
22   test.  We can go through each and every --

23          A    The primary one, the one that jumps to  
24   mind, is the Corrective Action/Preventive Action, not  
25   looking at out of specification results as thoroughly --



1 MR. ANDERTON: Pete, what are you doing?

2 MR. MILLER: I'm helping him. You asked  
3 me a minute ago to help him with documents. I'm  
4 helping him with documents.

5 MR. ANDERTON: Pete, we work with  
6 exhibits in this context. You don't just sit down  
7 in front of a witness and start randomly putting  
8 documents --

9 MR. MILLER: I'm not randomly doing  
10 anything. He brought documents at your request  
11 today. These are documents that he brought at  
12 your request today and now he's trying to answer  
13 your question.

14 MR. ANDERTON: I asked him a question.  
15 He's trying to answer it. If he wants to review  
16 documents he'll let me know, Pete.

17 MR. MILLER: Well, I'm objecting --

18 MR. ANDERTON: Put the binder away.

19 MR. MILLER: It requires --

20 MR. ANDERTON: Put the binder away.

21 MR. MILLER: I'm not putting the binder  
22 away. If the man wants to look at the binder --

23 MR. ANDERTON: I'm going to reach across  
24 the table -- Pete.

25 MR. MILLER: He's going to reach over and

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1 grab it and if you need it to answer the question  
2 you ask for it and he'll give it right back to  
3 you. Watch how this works.

4 BY MR. ANDERTON:

5 Q Mr. Farley --

6 MR. MILLER: Would you like to see the  
7 binder, Mr. Farley, to answer the question to be  
8 fair?

9 THE WITNESS: I'm not sure, but I didn't  
10 touch the binder.

11 MR. MILLER: Well, it doesn't matter who  
12 touches the binder. You just answer the question.

13 THE WITNESS: I want to think about it  
14 for a minute. I want to hear the question again  
15 and I want to think about my answer and then maybe  
16 I'll ask to see some documents.

17 BY MR. ANDERTON:

18 Q Okay. How was Digitek adulterated?

19 A And my answer was generally not being  
20 manufactured in compliance with GMPs. And then I think  
21 you said specifically point out the instances.

22 Q Well, let me ask it a different way, or  
23 another question. Never mind. You use -- if you'll  
24 turn to page 19 of your report, first conclusion.

25 A I'm on 19.

1 Q And you -- the last sentence you talk  
2 about deviation -- or I'm sorry -- you talk about  
3 violations and then you go on to say in the last  
4 sentence, All of these are shown to recur, thereby  
5 indicating that no corrective actions were made.

6 Did I read that last sentence correctly?

7 A I'm looking for where --

8 MR. MILLER: Which paragraph?

9 Q Page 19, the first conclusion.

10 MR. MILLER: Thank you.

11 Q I apologize.

12 A I'm going to read the paragraph to myself.

13 Q Take your time.

14 A I've read it.

15 Q Okay. The last sentence -- in the first  
16 sentence you talk about -- I'm sorry. In the second  
17 sentence you talk about violations. And then in the end  
18 of the paragraph you say all of these, all of these, are  
19 shown to recur, thereby indicating that no corrective  
20 actions were made.

21 Did I read that last sentence correctly?

22 A Yes.

23 Q So it's your testimony that every single  
24 violation recurred.

25 A That is what I concluded after reading

1 District Director Douglas Ellsworth's warning letter.

2 Q Every single one?

3 A He says -- I conclude that from it. He  
4 says these -- he mentions in the warning letter such and  
5 such and these continue to recur, you have made no  
6 effort to -- I forget the exact wording, but we can get  
7 it and I can tell you. But he says they're recurring.

8 Q What warning letter are you referring to?  
9 There's no warning letter after the 2008 inspection.

10 A No. Douglas Ellsworth's warning letter.  
11 98 documents, I just --

12 MR. MILLER: This paragraph doesn't  
13 mention the 2008 inspection.

14 A This paragraph refers to my overall  
15 conclusion --

16 Q Okay.

17 A -- of the company itself. I'm not  
18 directing that to any inspection. But the recurrence is  
19 what I read plus what -- and I don't know Douglas  
20 Ellsworth. I'm just mentioning his name because he's  
21 the district director.

22 Q Okay. The last sentence where you say, no  
23 corrective actions were made, our discussion of the 2007  
24 inspection and EIR shows that that's simply not  
25 accurate, doesn't it?

1           A    It -- my interpretation, if the corrective  
2   actions worked you wouldn't have a recurrence of the  
3   problem.  So therefore, they didn't work.

4           Q    So we are talking about 2008.

5                   MR. MILLER:  Object to form, misstating  
6   previous testimony.

7                   MR. ANDERTON:  No, Pete.  This is in  
8   forward.  It's the calendar.

9           Q    If you are assessing whether the  
10   corrections in the 2007 inspection worked you've got to  
11   go forward, right?

12          A    Yes.

13          Q    That would lead us into 2008.

14          A    Yes.

15          Q    So there was no warning letter after the  
16   2008 inspection.

17          A    I'm trying to think of the date of the  
18   last warning letter.  And your question was?

19          Q    So we're talking about 2008.  If your --  
20   your use of the term recur means you're talking about  
21   2008, right?

22          A    Yes.

23          Q    That was three minutes of too much work.

24          A    I just want to make sure that I'm giving  
25   you the right answer --

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1 Q I understand.

2 A -- for everyone's sake.

3 Q And if it's recurred -- you understand the  
4 difference between recur and continue?

5 A Yes.

6 Q So if it's recurred that means it's  
7 happening again, not --

8 A Yes.

9 Q -- continued to happen since the last  
10 time.

11 A Yes.

12 Q So it isn't true to say that something  
13 that recurs means no corrective action was made. I can  
14 correct something and if it happens again it happens  
15 again.

16 A You try corrective actions and at some  
17 point in time they didn't work.

18 Q At some point in time it happened again.

19 A Yes.

20 Q That doesn't mean no corrective actions  
21 were made, does it?

22 A They weren't effective. They didn't last.  
23 I'm --

24 Q How do you know -- how do you know that  
25 the violation or the circumstance didn't occur for a

1 different reason?

2 MR. MILLER: Object to form, asked and  
3 answered.

4 A Some of them are the same. They're almost  
5 word for word the same infraction, the same reasoning.

6 Q All based on your review of the FDA  
7 documents?

8 A Of the whole 93 documents, many of which  
9 were --

10 Q None of which were production records for  
11 any product manufactured by Actavis, correct?

12 A One was the batch record.

13 Q The single batch record of one lot.

14 A That exception.

15 Q Okay. With that exception of that single  
16 batch, none of which were production records, correct?

17 A Correct.

18 Q Do you know when Digitek was recalled?

19 A I read it in the data. I'm at a loss  
20 offhand for the exact date.

21 Q If I say April 28th -- I'm sorry --  
22 April 25, 2008, do you have any reason to dispute that?

23 A I have no reason to dispute that.

24 Q Does that sound about right, April 25?

25 A Sounds about right.

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1 Q Okay. Do you know when the inspection  
2 ended?

3 A May of '08. Is that the one you're  
4 referring to?

5 Q Yes, May 20 of '08.

6 A Yes.

7 Q Turn to the last conclusion in your  
8 report.

9 A The very top of page 20 above my  
10 signature?

11 Q Correct.

12 A I have it.

13 Q It reads, Patients have no assurance of  
14 the proper quality of the Actavis products since they  
15 were produced under non-compliant conditions in  
16 violation of FDA regulation.

17 A Yes.

18 MR. MILLER: You left out the word many.

19 Q I apologize. Since many were produced  
20 under non-compliant conditions in violation of FDA  
21 regulations.

22 With that correction did I read that  
23 correctly?

24 A Yes, you did.

25 Q Which many?



1 A Which many?

2 Q Yeah. Which products?

3 A Whatever were produced in that plant  
4 during that time period. And I don't know all the  
5 production records as to what was made during that time.  
6 They were in a period of being non-compliant.

7 And I'm saying whatever they made during that  
8 time when their quality system was not functioning --  
9 Erin McCaffery said total failure; I'm saying not  
10 functioning well -- that you can't trust the quality of  
11 any product that was made during that time.

12 Q Why did you say many and not all?

13 A All would have been a very, very inclusive  
14 term and I didn't really know that it was all.

15 Q You just --

16 A So I put many.

17 Q So you don't really know that it's all.

18 A I don't know that it's all. That's why I  
19 didn't write all.

20 THE VIDEOGRAPHER: I'm going to go off  
21 the record to change tapes, sir. It's 5:35. One  
22 moment.

23 (Off the record.)

24 THE VIDEOGRAPHER: This is the beginning  
25 of Tape No. 8. It's 5:36 p.m.

1 MR. ANDERTON: Mr. Farley, subject to my  
2 review of the documents that were produced today,  
3 the draft reports and such, at the moment I don't  
4 believe I have any further questions. I'm going  
5 to leave the record -- Pete -- Mr. Miller is going  
6 to make a responsive comment. So don't get up and  
7 leave just yet.

8 THE WITNESS: I'm here.

9 MR. ANDERTON: So I reserve the right to  
10 reconvene this session on behalf of Defendants in  
11 the event our review of those documents suggests  
12 further examination based on those documents as  
13 necessary.

14 THE WITNESS: Yes. I understand.

15 MR. MILLER: To the extent your review of  
16 documents you -- if you believe from that review  
17 that you need to come back then I would say that  
18 we restrict it obviously only to his documents.

19 But my position would be that I offered  
20 up a vast majority of those documents before lunch  
21 and certainly we could have gone over the rest of  
22 them during lunch.

23 I think you've had ample opportunity to  
24 review them. But we'll look at this more as we go  
25 forward and decide.

1 MR. ANDERTON: Well, actually -- before I  
2 close the record -- I almost -- let's not mess  
3 this up. I don't have copies of those.

4 MR. MILLER: You do. It's on the thumb  
5 drive.

6 MR. ANDERTON: I need hard copies if I'm  
7 going to introduce them as exhibits. If you want  
8 to minimize the -- I'm going to mark them and  
9 introduce them.

10 MR. MILLER: All right. But you asked  
11 for the thumb drive and we gave them to you on the  
12 thumb drive.

13 MR. ANDERTON: I understand. I don't  
14 have --

15 MR. MILLER: I mean, there's not a  
16 requirement to give you multiple copies. You've  
17 got copies. And if --

18 MR. ANDERTON: Can I take that and get  
19 copies made, Pete?

20 MR. MILLER: Yes.

21 MR. ANDERTON: Okay.

22 MR. MILLER: Well, I've got questions  
23 before we close this.

24 MR. ANDERTON: Well, I don't have time.  
25 This --

1 MR. MILLER: I've got five minutes of  
2 questions.

3 MR. ANDERTON: Pete --

4 MR. MILLER: You can sit here or not sit  
5 here. I've got five minutes of questions.

6 MR. ANDERTON: We're past 5:30. We've  
7 got a PTL that says we cut off at 5:30.

8 MR. MILLER: Well, I mean, I've got five  
9 minutes.

10 MR. ANDERTON: So it sounds -- no, Pete.  
11 I'm not missing my flight. I don't have --

12 MR. MILLER: You're not going to miss  
13 your flight. I'm going to ask four questions.

14 MR. ANDERTON: I don't have the ability  
15 to --

16 MR. MILLER: I'm going to ask these  
17 questions. So you do have the ability. Just pack  
18 up while I'm -- I'll be done before you get  
19 everything packed up. Okay? Allow me to ask  
20 these questions.

21 MR. ANDERTON: Okay.

22 MR. MILLER: Thank you.

23 Mr. Farley --

24 MR. ANDERTON: Wait. Before you do that,  
25 we're going to mark these documents. So if you

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1 want to -- I mean, she's got to mark these  
2 exhibits.

3 I suggest actually we just allow her to  
4 mark those. She'll take them. I'll get copies  
5 from her and you can print new copies.

6 MR. MILLER: I'll get copies from her as  
7 well. That's fine. I have no problem with that.

8 MR. ANDERTON: Okay.

9 MR. MILLER: But let's mark them after I  
10 get done with my time.

11 MR. ANDERTON: Well, you can mark those  
12 after we leave.

13 THE COURT REPORTER: I can.

14 MR. ANDERTON: Okay.

15 MR. MILLER: Perfect.

16 - - - - -

17 CROSS EXAMINATION

18 BY MR. MILLER:

19 Q Mr. Farley, you were asked extensively  
20 about the EIR with the September 2007 FDA inspection.

21 Do you recall that?

22 A Yes.

23 Q And you were asked several times about the  
24 corrections, voluntary corrections, that were put in  
25 place from the 15 observations that were made on the

1 previous inspection, correct?

2 A Yes.

3 Q And because observation -- or correction.  
4 Because corrections have been proposed and implemented  
5 as noted by the FDA, that doesn't mean that they are  
6 successful; is that correct?

7 A That's correct.

8 Q Okay. And ultimately following regulatory  
9 investigations will determine if they were successful or  
10 not; is that correct?

11 A That's correct. And that's the point I  
12 was trying to make.

13 Q Thank you. And on your conclusions, sir,  
14 looking at that first paragraph of conclusions -- and I  
15 won't read them all. But that first sentence of the  
16 first conclusion, Based on the review of the documents  
17 listed in this report I conclude that Actavis had  
18 essentially no quality control over the products it  
19 produced and shipped.

20 Did I read that correctly, sir?

21 A Yes.

22 Q And you base that opinion on all the  
23 documents that you reviewed, correct?

24 A Yes.

25 MR. ANDERTON: Peter, are you leading --

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1 wait.

2 MR. MILLER: You can object.

3 MR. ANDERTON: I am objecting. You've  
4 got to give me a chance.

5 MR. MILLER: All right. I didn't hear  
6 the word objection. I'm sorry.

7 MR. ANDERTON: Objection. You're leading  
8 the witness.

9 BY MR. MILLER:

10 Q Was speculation required in any way in  
11 determining your opinions?

12 A My speculation?

13 Q Yes.

14 A No. It was based on opinions from my  
15 experience.

16 Q Fair enough. And that's true with all the  
17 opinions that you have in this report; is that correct,  
18 sir?

19 MR. ANDERTON: Objection. Again, are  
20 you -- is this cross-examination? Direct  
21 examination? What --

22 MR. MILLER: I didn't hear objection.

23 MR. ANDERTON: Objection, leading.

24 MR. MILLER: Thank you.

25 BY MR. MILLER:

1 Q Did you have to speculate in any way on  
2 all the opinions in this report?

3 A I didn't speculate on anything. I used my  
4 opinion based on my best judgment and my years of  
5 experience and knowledge.

6 Q Did you feel you had a satisfactory amount  
7 of information to make the opinions that you've rendered  
8 in this report?

9 A Yes, I do.

10 Q Okay. Was anything said today that  
11 affected any of your opinions?

12 A No. While various other documents that I  
13 had not seen were mentioned they, I believe, would not  
14 affect my opinions.

15 Q Okay. And were all these opinions given  
16 to a reasonable degree of scientific certainty?

17 A Yes.

18 MR. MILLER: That's all the questions I  
19 have.

20 - - - - -

21 REDIRECT EXAMINATION

22 BY MR. ANDERTON:

23 Q Okay. I have a couple follow-up  
24 questions, Mr. Farley.

25 A I'm here.



1 Q Is GMP compliance evaluation a science?

2 A It's not considered a science. It's a  
3 system like total quality management is a system. It's  
4 the FDA's equivalent of total quality management.

5 Q So when you were asked a moment ago  
6 whether they were rendered with a reasonable degree of  
7 scientific certainty, what did you mean when you said  
8 yes?

9 A I interpreted that as Peter Miller was  
10 asking me about my scientific knowledge, my work  
11 experience. That's how I interpreted that when I said  
12 yes. It's my scientific certainty.

13 Q Yeah, but in the area of GMP compliance  
14 it's not scientific knowledge. It's, as you said,  
15 specialized perhaps but not scientific.

16 A Well, chemists, physicists and some other  
17 scientists have what we call the scientific way of  
18 thinking, the logical way of thinking. And we're rather  
19 proud of it, in fact. And when I was asked if it's  
20 scientific or whatever deduction, I said yes, meaning my  
21 scientific way of thinking.

22 MR. ANDERTON: Thank you. I have no  
23 further questions. And again, I reserve the right  
24 to reconvene based on --

25 THE WITNESS: Yes.

1 MR. ANDERTON: But we're going to mark --

2 THE VIDEOGRAPHER: Read and sign?

3 MR. MILLER: Yes.

4 MR. ANDERTON: We're going to mark the  
5 documents in this binder -- how many are there?

6 MR. MILLER: How many? Several. You  
7 want to go by tab? Each one of these is an  
8 individual file on that thumb drive. Like you're  
9 going to see these are several documents. But  
10 each one of those is going to be --

11 MR. ANDERTON: Okay.

12 MR. MILLER: -- a document on the thumb  
13 drive. We'll just go by tabs. We're going to  
14 group each one in tabs.

15 MR. ANDERTON: Okay. So you can mark  
16 the -- each tab in that white binder as an  
17 individual document. And those can be -- well,  
18 let's call it Defendants' Exhibit 100, just to be  
19 safe. And start with 100 and go up.

20 And then the draft reports is, what I'll  
21 call them -- I'm not sure they're actually drafts  
22 according to Mr. Farley. There are three. You  
23 can make those 45A, 45B and 45C.

24 THE COURT REPORTER: Okay.

25 MR. ANDERTON: Okay? And then if you

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1 will -- we'll contact you to get copies.

2 THE COURT REPORTER: Okay.

3 MR. ANDERTON: Okay? Thank you very  
4 much.

5 THE VIDEOGRAPHER: All right. The  
6 deposition is concluded and it is 5:44 p.m.

7 (Defendants' Exhibit Nos. 45A, 45B, 45C, 100, 101,  
8 102, 103, 104 and 105 were marked.)

9 (The proceedings were concluded at 5:44 p.m.)

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James J. Farley

June 28, 2010

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1 ERRATA SHEET

2

3 I, the undersigned, JAMES J. FARLEY, do hereby  
4 certify that I have read the foregoing deposition and  
5 find it to be a true and accurate transcription of my  
6 testimony, with the following corrections, if any:

7

8	PAGE	LINE	CHANGE	REASON
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JAMES J. FARLEY

Date

24

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ASG

CERTIFICATE

GEORGIA:

CHATHAM COUNTY:

I, Angela S. Garrett, Certified Shorthand  
Reporter for the State of Georgia, do hereby certify:

That the foregoing deposition was taken before  
me on the date and at the time and location stated on  
Page 1 of this transcript; that the witness was duly  
sworn to testify to the truth, the whole truth, and  
nothing but the truth; that the testimony of the witness  
and all objections made at the time of the examination  
were recorded stenographically by me and were thereafter  
transcribed by computer-aided transcription; that the  
foregoing deposition, as typed, is a true, accurate, and  
complete record of the testimony of the witness and of  
all objections made at the time of the examination.

I further certify that I am neither related to  
nor counsel for any party to the cause pending or  
interested in the events thereof.

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1                   Witness my hand, I have hereunto affixed my  
2   official seal this 6th day of July, 2010, at Savannah,  
3   Chatham County, Georgia.

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5

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Angela S. Garrett, CSR, RPR

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## 1 D I S C L O S U R E

2 Pursuant to Article 8.B. of the Rules and  
3 Regulations of the Board of Court Reporting of the  
4 Judicial Council of Georgia, I make the following  
5 disclosure:

6 I am a Georgia Certified Court Reporter. I was  
7 contacted by my office of McKee Court Reporting, Inc.,  
8 to provide court reporting services for this deposition.

9 I will not be taking this deposition under any  
10 contract that is prohibited by O.C.G.A. 15-14-37(a) and  
11 (b).

12 I have no contract/agreement to provide reporting  
13 services with any party to the case, any counsel in the  
14 case or any reporter or reporting agency from whom a  
15 referral might have been made to cover the deposition.

16 I will charge its usual and customary rates to all  
17 parties in the case, and a financial discount will not  
18 be given to any party to this litigation.

19

20

21

22

23 \_\_\_\_\_ Date: July 6, 2010

24 Angela S. Garrett  
25 RPR, CCR-B2407

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION

MDL NO. 1968

---

VOLUME II

The continued videotaped deposition of JAMES J. FARLEY taken by counsel for the Defendants, Actavis Totowa, LLC, Actavis, Inc., and Actavis Elizabeth, LLC, pursuant to notice and by agreement of counsel, reported by Angela S. Garrett, CSR, RPR, B-2407, at the Embassy Suites, 145 Mulberry Boulevard, Savannah, Georgia, on January 19, 2011, commencing at 9:03 a.m.



1 APPEARANCES OF COUNSEL

2  
3 FOR THE PLAINTIFFS:

4 MIKE KERENSKY, ESQUIRE  
5 WILLIAMSON & RUSNAK  
6 4130 Yoakum Boulevard  
7 Houston, Texas 77056  
8 (713) 223-3330  
9 mike@jimmywilliamson.com

10 MEGHAN JOHNSON CARTER, ESQUIRE  
11 MOTLEY RICE, LLC  
12 28 Bridgeside Boulevard  
13 Mt. Pleasant, South Carolina 29464  
14 (843) 216-9383  
15 mjohnson@motleyrice.com

16 DON ERNST, ESQUIRE (Via telephone)  
17 ERNST & MATTISON, ALC  
18 1020 Palm Street  
19 San Luis Obispo, California 93401-3284  
20 (805) 541-0300

21 FOR THE DEFENDANTS, ACTAVIS TOTOWA, LLC, ACTAVIS, INC.,  
22 AND ACTAVIS ELIZABETH, LLC:

23 MATTHEW P. MORIARTY, ESQUIRE  
24 TUCKER, ELLIS & WEST, LLP  
25 1150 Huntington Building  
925 Euclid Avenue  
Cleveland, Ohio 44115-1475  
(216) 592-5000  
matthew.moriarty@tuckerellis.com

1 APPEARANCES OF COUNSEL (Cont'd)

2

3 FOR THE DEFENDANTS, MYLAN PHARMACEUTICALS, INC.,  
4 MYLAN, INC., MYLAN BERTEK PHARMACEUTICALS, INC., AND UDL  
5 LABORATORIES, INC.:

6

ALICIA J. DONAHUE, ESQUIRE  
SHOOK, HARDY & BACON, LLP  
333 Bush Street, Suite 600  
San Francisco, California 94104-2828  
(415) 544-1900  
adonahue@shb.com

7

8 ALSO PRESENT: Bill Kaska, Videographer

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1 I N D E X

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4 By Mr. Moriarty 333

5 CROSS EXAMINATION

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9 REDIRECT EXAMINATION

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11 Certificate of Reporter 457

12 (Reporter's Disclosure Statement  
13 attached to back of transcript.)

14 \* \* \* \* \*

15 E X H I B I T S

16 DEFENDANTS'  
17 EXHIBIT

18 NUMBER DESCRIPTION PAGE

19 23 Letter from Scott Talbot with final  
20 update for audit program 385

21 24 Form 484 for Sample 377410 388

22 25 Form 484 for Sample 448881 399

23 26 Form 484 for Sample 448892 399

24 27 Form 484 for Sample 453913 399

25 28 Form 484 for Sample 454866 399

## E X H I B I T S (Cont'd)

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EXHIBIT

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29	Form 484 for Sample 462746	399
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31	Form 484 for Sample 157503	399
32	Form 484 for Sample 157504	399
33	Form 484 for Sample 178890	399
34	Form 484 for Sample 178891	399
35	Celsis test results on three Digitek batches	401
63	Regulatory Procedures Manual, Chapter 4, Advisory Actions	370
69	UDL Laboratories Receiving Form dated 4/10/08	403
70	UDL Laboratories Receiving Form dated 2/28/08	403
71	UDL Laboratories Receiving Form dated 1/21/08	404
72	UDL Laboratories Receiving Form dated 6/21/07	404
74C	Notice to Take Deposition	445

1 THE VIDEOGRAPHER: Good morning. We're  
2 on record. It's 9:03 a.m. This is the deposition  
3 of James J. Farley in the United States District  
4 Court for the Southern District of West Virginia,  
5 Charleston Division, the Digitek Product Liability  
6 Litigation, MDL No. 1968.

7 It is Wednesday, January 19th, 2011. We  
8 are at Embassy Suites, 145 Mulberry Boulevard,  
9 Savannah, Georgia, 31322.

10 Would the counsel present please  
11 introduce yourself for the record, please.

12 MR. KERENSKY: Mike Kerensky and Meghan  
13 Carter Johnson for the plaintiffs --

14 MR. MORIARTY: Matthew --

15 MR. KERENSKY: -- and also Don Ernst, who  
16 is on speakerphone.

17 MR. MORIARTY: Matthew Moriarty for the  
18 Actavis defendants.

19 MS. DONAHUE: I'm Alicia Donahue from  
20 Shook, Hardy & Bacon for the Mylan defendants and  
21 UDL Laboratories.

22 THE VIDEOGRAPHER: Thank you.

23 Madam court reporter, would you swear the  
24 witness, please.

25

1 JAMES J. FARLEY

2 having been first duly sworn testified as follows:

3 EXAMINATION

4 BY MR. MORIARTY:

5 Q Now, Mr. Farley, I know you've been  
6 through depositions before. So let's just go over the  
7 rules very quickly. If you don't understand my question  
8 for whatever reason, you tell me and I'll make it clear  
9 to you. Okay?

10 A Yes, sir.

11 Q And if you need to take a break for  
12 whatever reason let us know and we'll do that.  
13 Typically we break every hour, hour and a half anyway.  
14 Okay?

15 A Yes, sir.

16 Q And if you need to look at a document  
17 we'll either give you one or you can get it out of your  
18 own supply of documents that you've reviewed and brought  
19 with you. Okay?

20 A Yes.

21 Q All right. Have you been -- have you had  
22 your deposition taken in any other litigation since my  
23 colleague, Mr. Anderton, took your deposition in June of  
24 2010?

25 A No, I have not.

1 Q Have you given any trial testimony since  
2 June of 2010?

3 A No, I have not.

4 Q Have you been sued as a plaintiff or  
5 defendant in any lawsuit?

6 A No, I have not.

7 Q All right. Since June 2010 have you met  
8 with any of the plaintiffs' lawyers in the Digitek  
9 litigation?

10 A Just last night, Meghan and Mike --

11 Q Okay.

12 A -- here. But other than e-mails and phone  
13 calls from Meghan in the past couple of weeks telling me  
14 that I would be called upon, no.

15 Q All right. So the only in-person meeting  
16 you've had with any plaintiffs' lawyers in the Digitek  
17 litigation was last night to prepare for today's  
18 deposition, correct?

19 A Yes.

20 Q All right. And other than Mike Kerensky  
21 and Meghan Johnson Carter was anyone present?

22 A No.

23 Q Did you take any notes of that meeting  
24 last night?

25 A Yes.

1 Q Do you have those notes with you?

2 A Yes.

3 Q Where are they?

4 A They're in my folder that I put on the  
5 chair.

6 Q Okay. Can I see those?

7 A Yes. I'll get up.

8 Q Sure. Don't forget to take your  
9 microphone off.

10 A Thanks for reminding me.

11 MR. MORIARTY: Don, can you hear?

12 MR. ERNST: Yes. Although, Matt, I'm  
13 going to call in and see if we can have a  
14 speakerphone brought down to the room. So that  
15 may happen in the next half hour. But you're fine  
16 now. Thank you. I appreciate it.

17 MS. CARTER: I've already talked to them.  
18 They'll have it here in 45 minutes.

19 MR. MORIARTY: Meghan talked to the  
20 management. They're bringing one.

21 BY MR. MORIARTY:

22 Q Okay. Can I see the notes that you took  
23 from the meeting yesterday?

24 A This is what Meghan drew to assure  
25 everyone that --



1 MR. KERENSKY: Go ahead.

2 A This is what Meghan drew to differentiate  
3 between the Little Falls and the Riverview facilities to  
4 make sure that the three of us all were on the same  
5 page, so to speak. And we were.

6 Q Okay. Can I tear this off the tablet, the  
7 rest of which seems to be blank?

8 A Yes, sir.

9 Q What other notes did you take?

10 A Here's a sheet. I wrote less than a mile  
11 apart when Meghan and Mike were on speaker talking to a  
12 gentleman about the difference between Little Falls and  
13 the Riverview facilities. I wrote less than a mile  
14 apart.

15 Q Okay.

16 A And then later on in the evening Mike told  
17 me his phone number in case I needed to reach him.

18 Q Do you know who the other gentleman on the  
19 phone was?

20 A I was introduced to him and I don't  
21 remember his name. I'm sorry.

22 Q Was it Mr. Ernst from California?

23 A I don't know. I would have to ask Mike  
24 for that. I should know. I just don't remember his  
25 name. I didn't take any notes.

1 Q Did you take any other notes?

2 A Tucker, Ellis.

3 Q Important to know who am, I guess. You've  
4 handed me another sheet that says EIR, July 10th, 2006,  
5 Exhibit 90. Review the 483s and EIR. Put in --

6 A Chronological.

7 Q -- chronological order.

8 A Chronological order.

9 Q Anything else?

10 A These are notes I made to myself. I don't  
11 even know whose phone number that is at the top. But  
12 they're little notes I made to myself that don't seem to  
13 be connected even to me at this moment.

14 Q Okay. So the phone number at the top of  
15 this page of notes is 805-441-0988. Have you talked to  
16 any lawyers from California regarding the Digitek  
17 litigation?

18 A No, I have not.

19 Q What does the shoddy, S-H-O-D-D-Y, refer  
20 to?

21 A I believe to put it in the context we were  
22 talking about my opinion of Actavis and I was making my  
23 notes. I was not yet speaking, but I wrote shoddy. And  
24 then when Meghan and Mike finished and looked my way I  
25 used that term. Something like that.

1 Q All right. Do you have any other notes  
2 from the meeting?

3 A No, sir.

4 Q All right. How much time have you spent  
5 reviewing materials and talking to lawyers since your  
6 last deposition in June of 2010?

7 A Since then -- I heard the question. I'm  
8 pausing to try to give you an accurate answer. 24 hours  
9 last week and whatever time we spent here yesterday.

10 Q Okay. So essentially you did almost no  
11 work on Digitek between your last deposition and last  
12 week, correct?

13 A Correct.

14 Q All right. And you spent 24 hours last  
15 week, right?

16 A Yes.

17 Q What are you charging me and my law firm  
18 for the time we spend today in this deposition?

19 A I don't know the answer to that and the  
20 reason I don't is because I'm doing this for Smart  
21 Consulting Group, which is Dr. Nigel Smart and his wife,  
22 Denise Smart. They're doing the billing. I know  
23 they're paying me 150 dollars an hour. I really don't  
24 know what they bill any attorneys.

25 Q Do you know what the total amount to date

1 that you have been paid on the Digitek litigation  
2 including 2009, 2010 and this year?

3 A Around 36,000 dollars, give or take 3,000  
4 on that.

5 Q Okay. Now, since your last deposition  
6 have you reviewed additional materials? I don't want to  
7 talk about the re-review of old materials. I want to  
8 talk about new materials.

9 A I'm pausing to give you an accurate  
10 answer. No, sir.

11 Q So we took the depositions -- the same  
12 week that you were deposed here we took the depositions  
13 of Karen Frank, Russ Soma and Mark Kinney in  
14 Philadelphia and New Jersey respectively.

15 Have you read any of their deposition  
16 testimony?

17 A No.

18 Q Have you reviewed the reports of Soma,  
19 Kinney, Frank or Bliesner?

20 A No.

21 Q Have you seen the reports of any defense  
22 experts in this case?

23 A No.

24 Q Some names would be Ron Snee, Lou M. Sell,  
25 Martha Bennett. Those would be three examples. Have

1 you seen their reports?

2 A None of them. I haven't heard of them.

3 Q Have you requested any additional  
4 materials since June 2010?

5 A No.

6 Q All right. Let's go into a couple of  
7 background things that weren't covered the last time.

8 A Yes.

9 Q Have you updated your resume' since June  
10 2010?

11 A No.

12 Q And remind me where you went to college.

13 A My primary degree is from La Salle College  
14 in Philadelphia. It's now La Salle University. And  
15 then my master's degree in physical chemistry was at  
16 St. Joseph's College, which is now St. Joseph's  
17 University. And my MBA in marketing and finance was at  
18 Temple University.

19 Q And St. Joseph's and Temple are the ones  
20 in Philadelphia?

21 A Oh, all my schools were in Philadelphia.  
22 Yes, sir.

23 Q Are you a member of any societies or  
24 professional associations?

25 A The American Chemical Society.

1 Q Is that it?

2 A I'm thinking. One other organization is  
3 called AOPA. It's Aircraft Owners and Pilots  
4 Association. And it's a rather well-known organization  
5 for pilots.

6 Q All right. But as far as your profession,  
7 it's really the American Chemical Society?

8 A Just the American Chemical Society.

9 Q And do you hold any certifications or  
10 licenses?

11 A No.

12 Q Do you have any special training in  
13 quality assurance as opposed to quality control?

14 A I'm thinking. Do I have special training  
15 in it. I've taught it, but within what I think of as  
16 special training, no.

17 Q Do you consider yourself an expert in  
18 quality assurance in the pharmaceutical industry?

19 A That's tough to answer yes or no because  
20 it lies within the definition of an expert. I believe  
21 I'm very knowledgeable about it. I have consulted  
22 people on it and I believe I have helped them in the  
23 consultation. I would have used the term expert,  
24 although there are various definitions of what an expert  
25 is.

1 Q Well, is your core expertise in quality  
2 control chemistry?

3 A It is -- it overlaps. It's like a Venn  
4 diagram. It's tough to pick one thing. It's analytical  
5 chemistry. It's physical chemistry. It's quality  
6 control, which is part of quality assurance.

7 It's most recently manufacturing in the last  
8 dozen years. I can't answer that directly yes or no. I  
9 hope that I -- with that little dissertation I put it in  
10 the proper perspective.

11 Q Do you have expertise in regulatory  
12 affairs?

13 A Yes.

14 Q So what year did you graduate from  
15 La Salle?

16 A 1957.

17 Q And did you go straight for your master's  
18 after that?

19 A I enrolled at St. Joseph's University at  
20 night and then since I had four years of ROTC my work  
21 time was interrupted with military. And after getting  
22 out of the Army I went back to what was then Smith,  
23 Kline and French and continued my studies at night at  
24 St. Joseph's, receiving my degree in 1961.

25 Q When were you in the Army?

1 A 1958.

2 Q Just the one year?

3 A Yes.

4 Q And what was your rank on discharge?

5 A Final discharge from Reserves was captain,  
6 but discharge from active duty was second lieutenant.

7 Q So once you finished the Army what was  
8 your employment for the first few years after?

9 A At what was then Smith, Kline and French  
10 Laboratories in Philadelphia.

11 Q What did you do for them?

12 A I was the research analytical chemist,  
13 developing analytical procedures for new compounds.

14 Q Did that involve validation of methods?

15 A That was before the GMPs came into play  
16 and validation was not a term that was used. In effect  
17 you did that, but you didn't say we'll validate it,  
18 because the GMPs came into play around 1964, '65, '66.

19 Q All right. And how long did you work at  
20 Smith, Kline?

21 A I'm pausing to give you accurate  
22 information. In 1961 I left to go to SKF, no connection  
23 to Smith, Kline and French. It's called The Ball  
24 Bearing Place, metals and lubricants. I simply wanted  
25 to see what else was around in the field.



1 Q In the field of chemistry?

2 A Yes.

3 Q So SKF was not a pharmaceutical company?

4 A Was not.

5 Q How long did you work there?

6 A Two years. And then while I liked what I  
7 did as a research chemist there, I decided I liked  
8 pharmaceuticals and wanted to get back to the  
9 pharmaceutical industry.

10 Q Where did you go?

11 A What was then Wyeth Laboratories.

12 Q What did you do for Wyeth?

13 A Senior analytical chemist, developing new  
14 methods that would be used for testing raw materials,  
15 compounds and submissions to the FDA.

16 Q And did you do validation when you were at  
17 Wyeth?

18 A I want to say I did, but it was still just  
19 coming into play. The term wasn't used as it is today.  
20 But the equivalent of a validation, making sure that  
21 this method will work for the intended use.

22 So I'm going to say yes, but at the same time  
23 say the term validation, it was verify, validate, make  
24 sure it's right. These are the terms that were used  
25 then.

1 Q For either Smith, Kline or Wyeth did you  
2 work in pharmacovigilance?

3 A No.

4 Q Did you work in regulatory affairs?

5 A No.

6 Q Did you work in quality assurance?

7 A Not directly.

8 Q All right.

9 A I interacted with them, but I was not in  
10 quality assurance. I was research.

11 Q How long did you work at Wyeth?

12 A Until 1966.

13 Q Then where did you go?

14 A The West Company, now called West  
15 Pharmaceutical Services.

16 Q How long did you work at West?

17 A Until 1982.

18 Q All right. Now, did you leave Smith,  
19 Kline voluntarily?

20 A Yes.

21 Q Did you leave SKF voluntarily?

22 A Yes.

23 Q Did you leave Wyeth voluntarily?

24 A Yes.

25 Q All right. What did you do for The West

1 Company?

2 A A variety of things. I started out  
3 supervising their quality control department. That was  
4 one of the reasons I left, because it was a supervisory  
5 position.

6 As the company grew, the department expanded  
7 and they did more research, I mentioned that we might  
8 have a separate research function since now I had  
9 quality control background and the research background.  
10 And they let me form a research and development group  
11 more officially than they had before.

12 Then -- and I'm a little vague on this because  
13 so many years. But I ended up as assistant director of  
14 laboratories as the company expanded and was involved in  
15 talking to the customers, all of whom were  
16 pharmaceutical firms who wanted to bring their products  
17 to the market, because they bought the rubber stoppers  
18 from us.

19 And I interacted highly with various people,  
20 various firms that got more involved in the regulatory  
21 aspect in that our products, which were components of  
22 their final product, had to meet regulations.

23 Q All right. Did The West Company  
24 manufacture solid oral dose pharmaceuticals when you  
25 worked for them between '66 and '82?

1 A No.

2 Q Did you work on the manufacture of solid  
3 oral dose products when you were at Wyeth?

4 A Do you mean making them, putting them  
5 together --

6 Q Yes, sir.

7 A -- or if -- not putting them together. I  
8 analyzed them.

9 Q Okay. I'm asking whether you helped  
10 manufacture them.

11 A No.

12 Q Did you help in any way manufacturing when  
13 you were at Smith, Kline?

14 A In testing materials at points along the  
15 way to make sure a process was working well, but I  
16 myself was not in manufacturing.

17 Q All right. Did you go to the FDA in 1982?

18 A No.

19 Q Where did you go after The West Company?

20 A I formed my own training business.

21 Q What was it called?

22 A James Farley Seminars.

23 Q And how long did you run James Farley  
24 Seminars?

25 A That was off and on until 1987. I say off

1 and on. The business was on, but I realized at that  
2 point that I wasn't running my own business as well as I  
3 thought I could and I wanted to get back to the more  
4 steady income.

5 Q All right. So in 1987 did you go to the  
6 FDA?

7 A No, sir.

8 Q Where did you go in '87?

9 A Federal Government, Department of Defense  
10 in Philadelphia.

11 Q What did do you do for the Department of  
12 Defense?

13 A I was working with -- some parts were  
14 fabrics, but other parts were testing drugs that the  
15 Department of Defense would use. They were usually  
16 drugs beyond the expiration date that the DOD,  
17 Department of Defense, wanted to use for the military.  
18 And we would analyze them to verify that they were still  
19 good even though beyond expiration date.

20 Q Okay. So those years from '82 through --  
21 how long were you with the Department of Defense?

22 A I was with the Department of Defense  
23 approximately one and a half years.

24 Q So sometime in '88 or '89?

25 A June of '89, to be precise.

1 Q All right. And so the years '82 when you  
2 were with West, you had your training business and then  
3 Department of Defense, you were not involved in the  
4 manufacture of solid oral dose pharmaceutical products?

5 A Not involved in the manufacture directly.

6 Q All right. And then what did you do in  
7 '89?

8 A I realized that while I now had steady  
9 income coming in, which is what I wanted, that I really  
10 wanted to get back to pharmaceuticals. And transferring  
11 from one federal organization to another was relatively  
12 easy. And the FDA was not even across town in  
13 Philadelphia. I applied there and they accepted me and  
14 I started working there.

15 Q Okay. So in your career have you ever  
16 done blend uniformity testing for solid oral dose?

17 A Testing?

18 Q Yeah, blend uniformity testing.

19 A I believe I have tested it; although I'm  
20 at a loss to say when and where.

21 Q Have you been involved in content  
22 uniformity testing of solid --

23 A Yes.

24 Q -- oral dose --

25 A Yeah.

1 Q Where?

2 A At Smith, Kline and at Wyeth. I'm trying  
3 to think, but definitely there.

4 Q When you were at -- when you did content  
5 uniformity testing did you use United States  
6 Pharmacopeia methods?

7 A I don't remember if we did or not. You  
8 don't have to use a USP method. You use the method that  
9 is most appropriate and is approved by the FDA. So  
10 while I don't remember which one, it could have been a  
11 USP method. It could have been a validated company  
12 method.

13 Q Would you agree with me that if a company  
14 is not going to use USP methods to test its  
15 pharmaceutical finished products, then it has to use a  
16 method validated and approved by the FDA?

17 A Yes, for materials that are to be released  
18 to the consumer.

19 Q All right. Did you have law and evidence  
20 training at FDA?

21 A Yes.

22 Q And I assume that was so you would have  
23 some understanding not only of what the regulations said  
24 but how FDA interpreted them; is that correct?

25 A Yes.

1 Q How many times did you actually go out on  
2 an inspection when you were with FDA?

3 A I'm trying to give you an accurate answer.  
4 I would say approximately quarterly.

5 Q Quarterly?

6 A Quarterly, which would be four times a  
7 year. Is that -- that's the best I can zero in on that.

8 Q All right. If I were to go back somehow  
9 and be able to study the records of FDA and look at  
10 warning letters and 483s from that period of time, how  
11 many would have your signature on them?

12 A One warning letter would have my signature  
13 on it. The 483s, I don't remember but I wouldn't be  
14 surprised if none of them did because the investigator's  
15 signature is on them. Oh, the analytical chemist does  
16 sign. Yes. There would -- a couple. I really don't  
17 want to mislead you or myself with a number.

18 Q The warning letter that would have your  
19 signature, if I recall correctly from your earlier  
20 testimony, is that the one you did not draft, you signed  
21 because somebody was out of the office that day?

22 A My boss was out and he said, you're in  
23 charge of the district the whole week. And a warning  
24 letter came in. That typically is signed by the  
25 district director.



1                   And it is drafted by someone else, but it is a  
2 document that you, the person who signs it, read every  
3 word on and verify before doing it. So that's a -- is  
4 that a qualified yes?

5                   Q    I'm just asking if that's the instance.

6                   A    Yes.

7                   Q    Thank you. Have you ever done assay or  
8 content uniformity on Digoxin?

9                   A    I myself?

10                  Q    Yeah.

11                  A    No.

12                  Q    Have you supervised people doing assay or  
13 content uniformity on Digoxin?

14                  A    No.

15                  Q    Do you have any association whatever with  
16 assay or content uniformity on Digoxin?

17                  A    No.

18                  Q    When you did assay or content uniformity  
19 for any solid oral dose pharmaceutical product, did you  
20 ever use only single point UV testing?

21                  A    Would you tell me what you mean by single  
22 point UV?

23                  Q    Well, I'm not an analytical chemist, but  
24 I've had somebody tell me that that's how they analyzed  
25 a particular product. Okay? Not HPLC or any of those

1 things. They used the single point UV. Okay?

2 Do you know what that is?

3 A I would be speculating. If I could  
4 explain what is normally done -- would you like me to do  
5 that?

6 Q Nope. So you're not familiar with single  
7 point UV testing --

8 A If it's the single point -- oh, I'm sorry.

9 Q -- as the sole method for content  
10 uniformity of a pharmaceutical product?

11 A I know people have done single point UV.  
12 My personal opinion is you should do the complete scan  
13 and measure a couple of points to look for the shape of  
14 the curve to give you a better instance. So what I'm  
15 saying is I didn't do it -- excuse me -- because I don't  
16 feel that's the real accurate method.

17 Q It's not reliable, in other words?

18 A I would say you don't know the reliability  
19 of it and certainly the complete spectrum and taking  
20 readings at different points I believe would be more  
21 reliable.

22 Q Okay. In your -- in your -- in the last  
23 session of your deposition we marked an exhibit, 46. It  
24 was an article that you co-authored with a lawyer here  
25 in Savannah.

1 Do you remember that?

2 A With Gene Brooks?

3 Q Yes, sir.

4 A The article with Gene Brooks?

5 Q Yes.

6 A I co-authored that article with him.

7 Q All right. In that article you say that a  
8 laboratory must analyze the drug and test for its active  
9 pharmaceutical ingredient and for strength and purity.  
10 We'll get back to that in a little bit.

11 But it says here gas chromatography, liquid  
12 chromatography and microbiological tests are the three  
13 most common testing methods used for analysis, correct?

14 A Yes.

15 Q Single point UV is not one you would list,  
16 right?

17 A It's used but I probably would not list  
18 it. And I don't remember if I did or not there.

19 Q I read you the sentence. Do you want to  
20 see your own article?

21 A Yes, please.

22 Q Right there where the highlighting is.

23 A I read the highlighted part.

24 Q Okay. And single point UV is not a test  
25 method that you listed in your article, right?

1           A     Correct, it is not what I listed in our  
2     article.

3           Q     Okay. Now, is it now universally accepted  
4     that a method used in forensic work has to undergo  
5     validation?

6           A     All methods have to undergo validation.

7           Q     All right. So when you were actively  
8     doing chemistry, analytical chemistry, how many times  
9     did you run a method before you considered it validated?

10          A     Validation of a method is not just a  
11     matter of how many times you run it.

12          Q     I understand that. But overall how many  
13     times do you think you went through the process before  
14     you and your company considered it validated?

15          A     Assuming the results came out as  
16     anticipated, a rule of thumb number is three. But that  
17     could be more or less, because there are -- there's a  
18     retrospective validation. There's other things we could  
19     bring in. But just keeping my question confined to what  
20     I'm considering now our area, rule of thumb would be  
21     three.

22          Q     All right. So let me make sure I  
23     understand. Let's assume you in your work as a chemist  
24     are going to perform an analysis on a product that  
25     you've never analyzed before, ever, okay, and you're

1 going to start to figure out how to analyze this. So  
2 you're going to create the method and you're going to  
3 run the method and you're going to validate it from  
4 scratch essentially. Okay?

5 How long in terms of time, in hours, days,  
6 weeks, months, would that typically take?

7 A I have to ask you a couple of questions  
8 before I answer that.

9 Q Well, I'll let you even though it's my job  
10 to ask. But go ahead.

11 A In order for the purpose of accuracy,  
12 we're talking about a chemical method, not a  
13 microbiological?

14 Q Chemical method on solid oral dose  
15 pharmaceutical products.

16 A A completed product like a tablet --

17 Q Yes.

18 A -- that has the active pharmaceutical  
19 ingredient?

20 Q Yes.

21 A And the excipients in it?

22 Q Yes.

23 A How long would it take me to validate it?

24 Q Yeah.

25 A If you're working straight through on

1 nothing else, it could range anywhere from two days to  
2 two weeks.

3 Q Okay. So if I told you that a lab ran  
4 content testing on a solid oral dose product, in the  
5 total time from scratch through validation, running the  
6 standards, running the blanks and the ultimate sample  
7 took a total of two hours, that would be inconsistent  
8 with your experience, wouldn't it?

9 A To validate the method?

10 Q To start from scratch --

11 A From scratch.

12 Q -- on a product that they had never tested  
13 before, to create the method, validate it, run the  
14 standards, run blanks and run a sample for forensic  
15 reporting purposes, total of two hours, that would be  
16 inconsistent with your experience, wouldn't it?

17 A I would use the word inconsistent as  
18 opposed to impossible, inconsistent, surprising.

19 Q Okay.

20 MR. MORIARTY: Don, did you say  
21 something?

22 MR. ERNST: Yeah, I did. I thought it  
23 was a compound question.

24 MR. MORIARTY: Okay.

25 MR. ERNST: I objected.

1 MR. MORIARTY: Okay.

2 BY MR. MORIARTY:

3 Q In your work either at FDA or a  
4 pharmaceutical company did you use the Regulatory and  
5 Procedures Manual in the FDA?

6 A Yes.

7 Q Did you use the Investigation Operations  
8 Manual?

9 A Yes.

10 Q In your opinions in this case are you  
11 relying on FDA Form 483s?

12 A Among other things, yes.

13 Q And some of those other things would be  
14 warning letters?

15 A Warning letters.

16 Q And EIRs?

17 A That's Establishment Inspection Report,  
18 yes.

19 Q And so when you are looking at those FDA  
20 documents you believe they're reliable?

21 A Yes.

22 Q And how often do you look at the FDA's Web  
23 site?

24 A I go to the FDA's Web site a couple times  
25 a week for different purposes each time.

1 Q All right. Do you consider it reliable?

2 A Most of the time. I've seen cases where I  
3 believe it hasn't been.

4 Q Can you identify any instances where you  
5 question the reliability of the FDA's Web site so far as  
6 it applies to this litigation?

7 A Could you give me that question again?

8 MR. MORIARTY: Can you read it back,  
9 Angela, please?

10 (The record was read back as requested.)

11 THE WITNESS: Not that I saw on the Web  
12 site, no.

13 BY MR. MORIARTY:

14 Q Okay. Do you have any teaching duties  
15 now?

16 A Now? No.

17 Q When was the last time you had teaching  
18 responsibilities?

19 A The year 2000 in the Philadelphia area.

20 Q Doing what?

21 A I was teaching in the Graduate School of  
22 Pharmacy at Temple University, teaching -- excuse me --  
23 process validation and another course was NDA  
24 submissions. I believe I was also teaching at a Penn  
25 State Philadelphia area campus management.



1 Q Okay. In your career as a consultant have  
2 you ever consulted for Actavis, Mylan, UDL or Amide?

3 A No.

4 Q Do you know the difference between  
5 possibility and probability?

6 A I believe I do.

7 Q All right. Probability would be more  
8 likely than not?

9 A Yes.

10 Q Possibility would be speculation,  
11 generally less than 50 percent chance of occurring?

12 A I haven't equated possibility with the  
13 word speculation, but I agree with the probability.

14 Q Okay. Now, before you drafted your  
15 original report in this case, which I believe was  
16 Exhibit 45 -- I'd have to make sure; hang on a second  
17 here -- yeah, Exhibit 45, I assume you read all of the  
18 material that had been supplied to you, correct?

19 A Yes.

20 Q And at that point did you know that the  
21 purpose of the report was essentially to put lawyers  
22 like me for the pharmaceutical defendants on notice of  
23 what your opinions were so that we had some idea what  
24 you were going to say when we came and questioned you?

25 A My answer is yes, but I would word it as

1 the purpose of the report was to render my opinion for  
2 anyone who cared to read it.

3 Q All right. And when was the last time you  
4 read your original report?

5 A Last week.

6 Q All right. And would you agree with me  
7 that nowhere in your original report, Exhibit 45, do you  
8 say that Digitek was in fact defective?

9 A I did not use those words.

10 Q All right. Now, this article, Exhibit 46,  
11 what was your role in writing this article as opposed to  
12 Mr. Brooks' role?

13 A I would like to take a minute to go back  
14 in the relationship. Gene Brooks is a person that we  
15 met on a vacation here in Savannah and he sort of clued  
16 us in on Savannah when we said we might consider moving  
17 here, it's a nice place.

18 And then Gene -- when we moved here Gene  
19 became a friend. And we meet periodically for lunch.  
20 Just talk about Savannah. And I don't even remember  
21 which one of us, but one of us at one time said, you  
22 know, we ought to put an article in some journal, let's  
23 get together and write something.

24 Whether he's the one that said with your  
25 background, Jim, and my law or whether I said with your

1 law and my background, I really don't remember. But we  
2 thought it would be a nice article to publish.

3 And (ck0 Jim Shepherd, he had just passed the  
4 Bar right around that time. So it's -- that was how  
5 that evolved, so to speak. That's the best answer I can  
6 give you on that.

7 Q Well, that gives me the evolution. But  
8 what was your role in the writing? I'm sure you two sat  
9 down and said you're going to do X and you're going to  
10 do Y. What was your role?

11 A In effect, Gene, you do the law stuff, Jim  
12 Farley, you do the pharmaceutical stuff.

13 Q Okay. So the statement, A laboratory must  
14 analyze the drug and test for its active pharmaceutical  
15 ingredient and for strength and purity, is that a  
16 statement that you wrote or that Gene Brooks wrote?

17 A I don't remember offhand, but it might  
18 have been Gene put it together and ran it by me and I  
19 might have agreed as is or modified it in some way.  
20 That's probably how it happened.

21 Q All right. So why did you or you and Gene  
22 say the laboratory must analyze the drug and test it for  
23 its API?

24 A So that you know that you have the proper  
25 drug. Am I answering your question properly?

1 Q Just answer it and I'll follow up. Why  
2 did you say that?

3 A Why did we say that?

4 Q A lab must analyze the drug and test it  
5 for its API and for strength and purity. Why?

6 A To be sure that it is what it is supposed  
7 to be.

8 Q Okay.

9 A Yeah.

10 Q So in other parts of this article you do  
11 talk about adulteration, correct?

12 A Yes.

13 Q So what you're advocating is to go beyond  
14 the regulatory definition of adulteration to testing to  
15 find out whether it is what it purports to be, correct?

16 A Yes.

17 Q Did you tell Mr. Brooks or did you  
18 contribute in any way to an analysis of the impact, if  
19 you will, or the meaning of GMP violations or recalls?

20 A In any way?

21 Q Yeah.

22 A We discussed it. I just am at a loss as  
23 to the exact nature of the conversation. But we  
24 discussed GMPs and what is a GMP violation. Yes, we  
25 did.

1 Q Okay. But did you discuss and did you  
2 contribute to writing about the actual impact, what does  
3 it mean when there is a GMP violation?

4 A I don't remember if we put that in there  
5 or not.

6 Q Do you consider yourself an expert on the  
7 legal ramifications of a violation of GMP?

8 A I'm not a lawyer. So I --

9 Q That's not what I asked.

10 A Well, that wasn't the whole sentence. It  
11 was I'm not a lawyer, therefore I don't consider myself  
12 an expert on legal ramifications.

13 Q All right. So when you were with these  
14 pharmaceutical companies in the years before you went to  
15 FDA, how much experience did you have with  
16 pharmaceutical recalls?

17 A Not much.

18 Q In your consulting work have you been  
19 asked to participate with your clients in working on  
20 recall issues?

21 A In some cases -- I'm pausing because I'm  
22 thinking of confidentiality.

23 Q I didn't ask for the name of a company.

24 A Okay.

25 Q I just right now I've asked --

1 A Yes, sir.

2 Q -- whether you've had experience in  
3 consulting with recalls.

4 A To a degree, yes.

5 Q All right. To your knowledge can FDA ask  
6 a pharmaceutical company to recall a product for  
7 virtually any reason?

8 A For virtually any reason? For -- I would  
9 say for a reason where they think there is potential for  
10 harm to the consumer. For any valid reason. I guess  
11 I'm getting a little tied up on that for any reason part  
12 of your question.

13 Q That's fine. That's fine. The FDA can  
14 ask a company to recall a product because of the  
15 potential for harm to consumers, correct?

16 A Yes.

17 Q They don't -- there does not have to be  
18 some proof before the recall that there's likely to be  
19 harm to consumers; is that right?

20 A Yes.

21 Q So in other words, neither FDA nor the  
22 pharmaceutical company have to come up with some proof  
23 that there is in fact out-of-specification and dangerous  
24 drug product in the marketplace and in the hands of  
25 consumers, right?

1           A     Before I say right, you're saying proof  
2     and I would use the term they have a valid reason,  
3     somehow, somewhere they have a valid reason for asking  
4     for a recall, would you recall such and such from the  
5     market. It's a very expensive thing to do and it hurts  
6     the company's reputation.

7           So you use the word proof. I'm saying the FDA  
8     has a valid reason to believe there's a possibility or  
9     probability that a consumer or some consumers will be  
10    injured, harmed and they say, we want you to recall  
11    that. I had to extend that to put my answer in the  
12    proper context.

13          Q     Okay. But you didn't answer my question.

14                MR. MORIARTY: Angela, can you read my  
15     question back, please?

16                (The record was read back as requested.)

17                MR. ERNST: I'm going to object. It's  
18     been asked and answered. He's answered the  
19     question. It's also compound.

20          A     I --

21          Q     Go on.

22          A     I hear it again and it's still -- I'm  
23     getting -- the difference between proof and valid reason  
24     to believe that there's a probability that something can  
25     happen. And --

1           Q    Let me ask it a different way.  There  
2   doesn't have to be actual scientific evidence before a  
3   recall that there is likely out-of-specification and  
4   dangerous drug product in the marketplace, correct?

5           MR. ERNST:  Objection, vague, ambiguous  
6   speculative.  Those are not terms that -- you're  
7   making those terms.  It's also compound.

8           MR. MORIARTY:  And I'm going to just say  
9   that we don't have speaking objections in this MDL  
10   and those aren't PTO 22 objections.  So if we're  
11   going to do this let's do it right.

12  BY MR. MORIARTY:

13           Q    Can you answer my question?

14           A    Could you tell me one more time, please?

15           MR. MORIARTY:  You better read it back,  
16   Angela.

17           (The record was read back as requested.)

18           A    Yes, correct.

19           Q    Okay.  Thank you.

20           MR. ERNST:  Objection, vague, ambiguous.

21           Q    Has any company that you either worked for  
22   or have consulted with been subject to a consent decree?

23           A    Yes.

24           Q    How about a seizure?

25           A    No.



1 Q How about 483s?

2 A Yes.

3 Q Warning letters?

4 A Yes.

5 Q Recalls?

6 A Yes.

7 Q Have you seen any -- have you -- I'm  
8 sorry. Let me rephrase that.

9 Have you been provided with any scientific  
10 information whatsoever that there was a spike in Digoxin  
11 toxicity at hospitals, nursing homes, poison control  
12 centers or outpatient facilities in -- at any point  
13 between 2005 and 2008?

14 A I'm not sure what you mean by Digoxin  
15 toxicity.

16 Q Do you have any idea what that means?

17 A You mean OD, overdosing, or too much  
18 strength? I mean, Digoxin when used properly is not  
19 toxic. And to say Digoxin toxicity, if you mean  
20 over-strength tablets -- I'm not -- let me not put  
21 words -- please tell me again.

22 Q Digoxin toxicity simply for the purpose of  
23 my question is somebody who has a toxic reaction to  
24 Digoxin, whether the -- regardless of what the dose is.  
25 Okay?

1           What I'm asking you is whether you've been  
2   provided with any scientific proof that there was a  
3   spike in Digoxin toxicity at any sort of medical  
4   facility in the United States between 2005 and 2008.

5           A    No.

6           MR. ERNST: I'm going to object, vague,  
7   ambiguous, calls for speculation.

8           MR. KERENSKY: When you get to a breaking  
9   point I'd like to take a break.

10          MR. ERNST: Scientific proof is not a  
11   standard.

12          MR. MORIARTY: Now is fine.

13          THE VIDEOGRAPHER: Okay. We're going off  
14   the --

15          MR. MORIARTY: Mike wants to take a  
16   break, Don. So we're going to do that.

17          THE VIDEOGRAPHER: Going off record.  
18   This is the end of Tape No. 1. 9:55.

19               (A brief recess was taken.)

20          THE VIDEOGRAPHER: Okay. We're back on  
21   record. It's 10:11 and this is the beginning of  
22   Media Unit No. 2.

23   BY MR. MORIARTY:

24           Q    Mr. Farley, this is Exhibit 57 from your  
25   first deposition. This is a Form 483, is it not?

1 A May I? Yes.

2 Q Okay. And the Form 483 itself says, The  
3 document lists observations made by the FDA  
4 representatives during the inspection of your facility.  
5 They are inspectional observations and do not represent  
6 a final agency determination regarding your compliance.

7 Is that what it says right at the top of the  
8 document itself?

9 A It should. It's standard procedure.

10 Q Okay. And to your knowledge does the  
11 Regulatory Procedures Manual say essentially the same  
12 thing?

13 A As I recall, yes.

14 Q All right. So Exhibit 63, which is  
15 Chapter 4 of the Regulatory Procedures Manual, in  
16 Section 4-1-1 on the second page of this document,  
17 fourth full paragraph, A warning letter is informal and  
18 advisory. It communicates the agency's position on a  
19 matter, but it does not commit FDA to take any  
20 enforcement action.

21 Did I read that correctly so far?

22 A Yes.

23 Q For these reasons FDA does not consider  
24 warning letters to be final agency action on which it  
25 can be sued.

1 Did I read that correctly?

2 A Yes.

3 Q Now, I want to ask you some questions  
4 about your report. Do you have a copy of it there?

5 A Yes.

6 Q All right. And that was Exhibit 45 in the  
7 last deposition, correct?

8 A If you say so. I don't remember the  
9 exhibit number of my report.

10 Q All right. Well, I have the original  
11 exhibits here if you need to look at them.

12 MS. CARTER: I think there was a 45A, B  
13 and C.

14 MR. MORIARTY: I think this was 45.

15 Q This one where it says, yes, 1 of 27. You  
16 got that in front of you?

17 A Yes.

18 Q Okay. Let's go to page 2 -- I'm sorry --  
19 page 3. And when I say page 3, you've got these pages  
20 numbered, right?

21 A Yes.

22 Q So on page 3 the -- one, two -- third  
23 statement under your experience with FDA it's talking  
24 about your directing the activities of the 30-member lab  
25 staff, correct?

1 A Yes.

2 Q Now, did your work in that regard include  
3 processing 484 samples?

4 A Yes.

5 Q You know what 484 --

6 A Yes.

7 Q -- samples are, correct?

8 A Surveillance samples.

9 Q FDA collects samples from companies or  
10 pharmacy shelves and tests them, correct?

11 A Yes.

12 Q Using USP or comparable methods, correct?

13 A Yes.

14 Q And they're running things like assay and  
15 content uniformity on them, right?

16 A Yes.

17 Q And do they typically do surveillance  
18 samples on products that have narrow therapeutic  
19 indexes?

20 A Yes.

21 Q Do you know if Digitek is one such  
22 product?

23 A I do.

24 Q Do you know whether your lab in  
25 Philadelphia ever did 484 samples on any Digoxin

1 products when you were there?

2 A I don't remember.

3 Q All right. Let's go to page 4. At the  
4 very bottom the last sentence refers to ineffective or  
5 unsafe product. Do you see that?

6 A Yes, I do.

7 Q All right. First let's talk about  
8 ineffective product. What do you mean by that?

9 A A product that does not do what it is  
10 supposed to do would be an ineffective product.

11 Q So, for example, a product that had too  
12 little of the active pharmaceutical ingredient might be  
13 ineffective, right?

14 A Might be.

15 Q All right. And then what do you mean by  
16 unsafe product?

17 A I want to read the whole context. Can I  
18 do that?

19 Q Sure. I just want to know what you mean  
20 by unsafe product.

21 A Unsafe would be something that would do  
22 harm to the consumer.

23 Q Okay. So theoretically a product that had  
24 too much of its active pharmaceutical ingredient could  
25 potentially be harmful to a consumer, correct?

1           A    That's one of the ways it could do harm to  
2   a consumer, yes.

3           Q    All right. Let's go out to page 17. Now,  
4   under comments in Section 5 in Paragraph A you use the  
5   term "total failure" several times.

6           Do you see that?

7           A    I see it.

8           Q    To your knowledge was there ever a final  
9   agency determination by FDA that there was a total  
10   failure of quality systems at Actavis?

11          A    Not using the terms total failure, but the  
12   consent decree told me that the FDA and the Court deemed  
13   they were incapable of making a quality product on their  
14   own.

15          Q    What consent decree?

16          A    The consent decree that Actavis received.  
17   I forget the date.

18          Q    The one that ended in 2002?

19          A    There was another one after that.

20          Q    When?

21          A    I'd have to look through.

22          Q    What I'm asking is to your knowledge is  
23   there some final agency determination that says in these  
24   words that you've used here there was a total failure of  
25   Actavis' quality systems?

1                   A    Not the agency. The agency did not use  
2   that term.

3                   Q    All right. Now, is it your opinion that  
4   Actavis made no products in 2006, '7 or '8 that were  
5   within their specifications?

6                   MR. ERNST: Object.

7                   A    I can't answer that if they made no  
8   products that were within their specifications. No. I  
9   would have to see the date on every single product they  
10  made in order to answer that.

11                  Q    Okay. Did FDA ever say in any document  
12  that there was a total failure of quality regarding  
13  Digitek?

14                  A    I did not see that from the FDA about  
15  Digitek.

16                  Q    Okay. Let's go to page 18. Go down to  
17  your Paragraph F on page 18.

18                  A    I'm there.

19                  Q    The end of your sentence says, All  
20  products, including Digitek, were adulterated. Do you  
21  see that?

22                  A    At the end.

23                  Q    Yes.

24                  A    Yes.

25                  Q    Can you show me a 483 or a warning letter



1 or any other FDA document that specifically says that  
2 Digitek was adulterated?

3 A That uses the term Digitek was  
4 adulterated?

5 Q Or something like that.

6 A I did not see it worded that way.

7 Q Okay. What was your understanding of why  
8 Digitek was recalled?

9 A My understanding was that there -- a  
10 combination of things. There were some adverse events  
11 reported from persons taking it. And upon FDA  
12 inspection some double thick or extra thick tablets were  
13 found. And at least one double thick tablet was found  
14 by a nurse or attendant person in a nursing home.

15 Q What is -- when was that -- well, let me  
16 break that down then in pieces. Okay? Let's get to the  
17 last thing you talked about first, this nursing home  
18 incident.

19 Was that tablet measured?

20 A Measured physically?

21 Q Yes.

22 A I believe but I am not sure. It went back  
23 to the company and they measured it and verified double  
24 thickness, but they did not analyze it.

25 Q What year was this?

1           A    I forget offhand. I'd have to check the  
2 records.

3           Q    Well, was it years before the recall or  
4 was it after the recall? Which the recall occurred in  
5 April of 2008.

6           A    I believe it was before the recall.

7           Q    You're talking about years before, the  
8 incident that was reported to the FDA, correct?

9           A    I'm associating with 2006, but I'd have to  
10 go through the files to verify that date.

11          Q    Well, let's just assume that it happened  
12 in 2005 or 2006. Did FDA order a recall when that  
13 occurred?

14          A    Based on the one incident?

15          Q    Yeah.

16          A    No.

17          Q    Did Actavis, or at the time Amide, report  
18 that incident to FDA in both a field alert and in its  
19 annual reporting?

20          A    I believe they did.

21          Q    And FDA was satisfied with the explanation  
22 given by Actavis in that it was an isolated incident,  
23 correct?

24                   MR. ERNST: Objection to form.

25          A    Yes.

1 Q All right. So can you show me a single  
2 document in all the documents that you reviewed to  
3 indicate that adverse event reporting had any influence  
4 on the Digitek recall?

5 MR. ERNST: Objection to form.

6 A In the 483s there's indicated that there's  
7 an inadequate adverse event reporting system at Actavis  
8 and that some events that should have been reported were  
9 not. So I would call that inadequate.

10 Q Didn't that happen in 2006 or 2007?

11 A Yes.

12 Q Didn't Actavis remediate that 483?

13 MR. ERNST: Objection to form.

14 A I don't believe it was satisfactory. They  
15 made some attempts, but they didn't do it well.

16 Q What does FDA do to a company when it is  
17 not satisfied with the remediation of a 483?

18 A They will go to a warning letter or they  
19 could just go to injunction procedure.

20 Q And if they -- if the company doesn't  
21 adequately remediate a warning letter what does the FDA  
22 do?

23 A They can -- they'll usually go to a  
24 consent -- they may go to a consent decree or they may  
25 shut them down.

1 Q Can you show me any evidence whatsoever  
2 that the FDA was not satisfied with the remediation of  
3 the adverse event reporting 483 that occurred in 2006 or  
4 2007?

5 MR. ERNST: Objection to form.

6 A Could you repeat that, please?

7 Q Okay. You've got a whole pile of  
8 documents here that you reviewed to prepare your report  
9 and your opinions. Show me somewhere in all that  
10 material anywhere that you can that the FDA was  
11 dissatisfied with Amide's remediation or Actavis'  
12 remediation of the 483 regarding adverse event  
13 reporting.

14 MR. ERNST: Objection to form, compound.

15 A I see a series of 483s, then a warning  
16 letter, then a consent decree. To me that says they're  
17 not pleased with it. Otherwise they wouldn't have done  
18 that.

19 Q Okay. I'm talking about one issue,  
20 adverse event reporting, pharmacovigilance. Okay?

21 A Yes.

22 Q Not some mountain of events. I want to  
23 isolate AERs. Is there anything in the FDA's  
24 documentation in 2008 when Digitek was recalled that  
25 refers to adverse event reporting for Digitek?

1 MR. ERNST: Objection to form.

2 A That refers only to the adverse event  
3 reporting and not to not using the proper methods and  
4 not investigating deviations or out of spec, only the  
5 adverse event reporting?

6 Q Adverse reporting.

7 A No.

8 Q And can you find me any documents in all  
9 the material you reviewed to indicate that the FDA was  
10 not satisfied with the remediation of the adverse event  
11 reporting --

12 MR. ERNST: Same objection.

13 Q -- adverse event reporting 483 back in '06  
14 or '07?

15 MR. ERNST: Objection to form.

16 A My indications was it was a combination of  
17 violations. But with regard to that one area, adverse  
18 event reporting, no, I did not.

19 Q Does the recall notice that was FDA  
20 approved say anything about adverse event reporting?

21 A No.

22 MR. MORIARTY: I happened to look at the  
23 transcript that is rolling up on the court  
24 reporter's computer screen and she has your name  
25 wrong, Don.

1 THE COURT REPORTING: No, I don't. I  
2 don't.

3 MR. MORIARTY: So we're going to correct  
4 that. Okay? I just want to make sure everybody  
5 knows. That should be Don Ernst, E-R-N-S-T.

6 THE COURT REPORTING: I know. That's  
7 coming up from the last deposition.

8 MR. MORIARTY: All right. And I'm not  
9 Mr. Anderton either.

10 THE COURT REPORTING: I know.

11 MR. ERNST: Thank you, Matt.

12 MR. MORIARTY: I was looking out for your  
13 interest, Don.

14 BY MR. MORIARTY:

15 Q Okay. Page 19 of your report, when a  
16 company is under consent decree don't they have to be in  
17 compliance with GMPs?

18 A You're asking me a question? You're  
19 not --

20 Q Well, at page 19 of your report under  
21 conclusions, Section 6, the fourth paragraph refers to  
22 the consent decree for ten consecutive years.

23 A Yes.

24 Q I assume you mean the one that expired in  
25 2002, correct?

1 A Yes.

2 Q And I'm asking you a question about that.  
3 To be under consent decree with the FDA don't you have  
4 to be in compliance with GMPs?

5 A The consultants that are brought in assure  
6 that the product leaving the facility is in compliance.

7 Q So is that a yes?

8 MR. KERENSKY: Wait, wait. You can't do  
9 that.

10 Q Okay. You go ahead.

11 MR. KERENSKY: Thanks.

12 A I just want to make sure that I put this  
13 in the proper perspective. The material is in  
14 compliance because the consultants are there making it  
15 in compliance.

16 Q Okay. So in other words, for these ten  
17 years that you're referring to at page 19 of your  
18 report, Amide was within -- acting within the GMPs?

19 A In whatever areas the consultants were  
20 functioning in helping them to do so they were.

21 Q Okay. And ultimately when they came off  
22 consent decree in 2002 it was because of sustained  
23 compliance with GMPs, correct?

24 A It is when the Court decides that they are  
25 capable of making a quality product themselves, yes.

1 Q Let's go to the very end of page 19.

2 Okay?

3 A Yes.

4 Q And you're talking about since the  
5 non-compliance problem was systemic all products,  
6 including Digitek, were adulterated as defined in  
7 Section 501 of the Food, Drug and Cosmetic Act.

8 Do you see that?

9 A Yes.

10 Q Okay. Is it your understanding that this  
11 litigation is about whether Digitek and other products  
12 at Actavis were considered adulterated under its  
13 regulatory definition?

14 A That's part of it. It's my understanding  
15 that there was a probability that some material produced  
16 by Digitek could harm a consumer.

17 Q Okay. Is there some statement in any FDA  
18 document that there is a probability that  
19 out-of-specification Digitek was shipped to the  
20 marketplace?

21 A Specifically as you worded that, no.

22 MR. ERNST: Objection to form.

23 Q To your knowledge did FDA say anywhere in  
24 a 483 or a warning letter that double thick tablets had  
25 in fact made it to the marketplace?



1 A In a 483?

2 Q Or a warning letter.

3 A Warning letter? No, they did not say it  
4 the way you just worded it.

5 Q Did the FDA anywhere in a 483 or warning  
6 letter say that out-of-specification Digitek tablets had  
7 made it to the marketplace or in the hands of consumers?

8 MR. ERNST: Objection to form.

9 A I'm pausing because they're not going to  
10 say that in a 483. The 483 is going to say what you're  
11 doing in the plant, the facility that's being inspected.  
12 It's not in the range of a 483 to say whether it's on  
13 the marketplace or not.

14 So that's why I'm looking surprised at the  
15 wording of the question, because the answer is not --  
16 it's like, of course, not, it won't in a 483.

17 Q Okay. Were you aware that FDA in the  
18 latter half of 2006 asked Actavis to bring in a  
19 consultant for some batch record reviews?

20 A Yes.

21 Q And the purpose of that in essence was to  
22 see according to the batch record reviews whether  
23 products were being made in accordance with GMPs,  
24 correct?

25 A Currently or before?

1 Q At the time.

2 A The previous batch review or the current  
3 batch record review? Because they do both.

4 Q Whatever. That was what FDA wanted  
5 Actavis to do, correct?

6 A Yes.

7 Q All right. This is Exhibit 23. Have you  
8 ever seen this before?

9 A Yes. I think. Yes.

10 Q The top sheet is a letter December --

11 MR. ERNST: To clarify, when you say have  
12 you seen this before can you identify that for me.

13 MR. MORIARTY: Exhibit 23.

14 MR. ERNST: Thank you.

15 Q The top sheet is a letter dated  
16 December 24th, 2007, to FDA from Scott Talbot at  
17 Actavis, correct?

18 A Oh. Yes.

19 Q All right. And attached is reports from  
20 Quantic Regulatory Services, correct?

21 A Yes.

22 Q Do you know anything about the reputation  
23 of Quantic Regulatory Services?

24 A I have done work for Claudio Pincus, who  
25 owns Quantic. I've done work for --

1 MR. KERENSKY: That's not the question.

2 A So, yes. They have a very good  
3 reputation.

4 Q Have you -- when you had Exhibit 23 did  
5 you look through the attachments that actually came from  
6 Quantic Regulatory Services?

7 A Much was redacted. But, yes, I did.

8 Q And do you know that they looked at a  
9 number of Digitek batches?

10 A I'd have to go back to the text. Because  
11 of all the redactions I can't see what they did or  
12 didn't do. Oh. I see some Digitek.

13 Q Well, did you ever count how many Digitek  
14 batches there were?

15 A I probably did at that time and I'm at a  
16 loss to tell you what that number is at this moment.

17 Q Okay. If I told you that 19 of the batch  
18 records that they looked at were ultimately amongst the  
19 recalled batches, would you have any reason to dispute  
20 that?

21 A I would not have any reason to dispute  
22 that.

23 Q And I think they looked at a total of 23  
24 Digitek batch records. Have you looked at any batch  
25 records of Digitek other than Batch 70924?

1 A Other than that batch, no.

2 Q It says on the first page of this exhibit  
3 in the letter from Mr. Talbot to FDA, On December 21st,  
4 2007, Quantic provided Actavis with a statement  
5 indicating the audit was complete and the manufacturing  
6 and the lab records will reliably confirm the identity,  
7 strength, quality and purity of the marketed products.

8 Do you see that?

9 A I see it.

10 Q Do you have any basis to disagree with  
11 Quantic Regulatory Services' conclusions regarding the  
12 batch record -- or the batch records that they reviewed?

13 A In one sense I do not have any reason to  
14 disagree with what Quantic said and found. But based on  
15 what I read in the 483s about the way they were  
16 manufacturing, it is surprising to me.

17 Q Okay. Now, this phrase that they use in  
18 this sentence, reliably confirm identity, strength,  
19 quality and purity, that mirrors the definition  
20 contained in the Food, Drug and Cosmetic Act regarding  
21 adulteration, correct?

22 A Yes.

23 Q So if you were to assume that Quantic was  
24 correct in reliably confirming identity, strength,  
25 quality and purity of at least the batches they

1 reviewed, assuming they were correct, those wouldn't  
2 even be considered adulterated. Isn't that true?

3 A If they confirm identity, strength,  
4 quality and purity they are normally not considered  
5 adulterated.

6 Q I'm handing you what's been marked as  
7 Exhibit 24, do you recognize that as a Form 484 from  
8 FDA?

9 A I don't.

10 Q Have you ever seen that document before?

11 A I'm taking a look in here. I'm having  
12 trouble reading the top where it's dark.

13 Q Well, let's go slowly -- let's go slowly  
14 through it. Okay? It's Sample 377410, correct? Up  
15 here.

16 A Oh. Sample No. 377 -- I'm just having  
17 trouble reading it because of the Xerox copy of it. But  
18 you're reading right here where I'm pointing in the dark  
19 area?

20 Q I have my own notes.

21 A Oh, okay. For Sample No. 377410.

22 Q Okay. And in the document, if you look at  
23 the first page, on February 9th, 2007, FDA secured two  
24 bottles of hundred count .125 milligram Digitek from  
25 Actavis. Do you see that?

1           A    I'm looking for -- I'm looking for where  
2   it says two bottles.  It's either in small print or my  
3   eyes are getting weak.

4           Q    I apologize.  I used to have highlighted  
5   versions of these so I could point right to the part of  
6   this document that you need to see.

7           MR. KERENSKY:  It's under description of  
8   sample two-thirds of the way down.

9           THE WITNESS:  Thank you.  I wasn't that  
10   far down.  I was still way up here.

11          MR. KERENSKY:  You want me to find it for  
12   you?

13          THE WITNESS:  I see it now.

14   BY MR. MORIARTY:

15          Q    Okay.  And then in the middle in the same  
16   area where Mr. Kerensky just pointed out, you see  
17   manufacturing code?  Right here.

18          A    Yes.

19          Q    That's Actavis Batch 70078A.  Do you see  
20   that?

21          A    Yes.

22          Q    Okay.  And you can look at this as  
23   thoroughly as you would like, but wouldn't I be correct  
24   in saying that after running thorough quality control  
25   chemistry testing on these tablets using USP methods,

1 FDA found them to be in compliance with their stated  
2 specifications?

3 A I'm looking to read this. I want to see  
4 where it says they used the USP method.

5 Q You take your time and look at the whole  
6 thing.

7 A Okay.

8 Q These are exhibits I've covered with other  
9 experts. If you doubt that I'm representing these to  
10 you accurately, you take all the time you want, because  
11 I've got about ten of these to go through.

12 A I'm not doubting your presentation. It's  
13 I want to make sure what I'm reading.

14 MR. KERENSKY: Let's take a little break.

15 MR. MORIARTY: We have 15 minutes on the  
16 tape and there's a pending question. As soon as  
17 he answers this question we can take a break.

18 MR. KERENSKY: Well, for the purpose of  
19 review I'm just saying let's stop the tape and  
20 just give him time. I'm not saying so I can talk  
21 to him. I'm saying let's go off the tape and see  
22 if we can find a sane way to go through that stack  
23 of documents.

24 MR. MORIARTY: That's fine.

25 MR. KERENSKY: Okay?

1 THE VIDEOGRAPHER: We're off record --

2 MR. MORIARTY: Oh, wait. Before we go  
3 off record -- you still on?

4 THE VIDEOGRAPHER: Yes, sir.

5 BY MR. MORIARTY:

6 Q I'm ultimately going to ask you about  
7 Exhibits 25, 26, 27, 28, 29, 30, 31, 32, 33 and 34. And  
8 I'm going to ask you essentially the same questions  
9 about --

10 A Yes.

11 Q -- all of them. Okay?

12 A Yes.

13 Q So if you want to look at all of them  
14 while we're on break I'll put the whole stack right  
15 here. Okay?

16 A Actually I forgot that question already.

17 MR. KERENSKY: The question -- are we  
18 still on record?

19 THE VIDEOGRAPHER: We are still on the  
20 record, yes.

21 MR. KERENSKY: The question as I  
22 understand that you want to ask is whether or not  
23 these documents show that the FDA tested the  
24 samples that they took and found them to be in  
25 compliance with their specifications.



1 Is that right?

2 MR. MORIARTY: Yes, sir.

3 MR. KERENSKY: Okay. All right. Let's  
4 go off the record.

5 THE VIDEOGRAPHER: We're off the record,  
6 10:47 a.m.

7 (A brief recess was taken.)

8 THE VIDEOGRAPHER: All right. We're back  
9 on record. Back on record. It's 11:05 a.m.

10 MR. KERENSKY: We took a break. And we  
11 are stipulating for the purposes of this  
12 deposition that Exhibits 24 through 34 -- is that  
13 the range, is that the correct range --

14 MR. MORIARTY: Yes, sir.

15 MR. KERENSKY: -- represent testing done  
16 by the FDA on Digitek tablets wherein the FDA  
17 found that the Digitek tablets were within  
18 specification.

19 MR. MORIARTY: Okay.

20 MR. KERENSKY: Okay. So no need to go  
21 through each and every one. We're -- and you  
22 can -- he's going to assume that to be true and  
23 you can ask him questions from there.

24 MR. MORIARTY: Okay.

25 BY MR. MORIARTY:

1 Q From the two exhibits that you did review,  
2 which were 24 and 25, that is correct, isn't it --

3 A Yes.

4 Q -- that FDA did 484 sampling, tested them  
5 and they complied with the specs, correct?

6 A Yes.

7 Q All right. Now, when FDA runs tests under  
8 the 484 program they can test assay, content uniformity,  
9 dissolution and impurity, correct?

10 A Yes.

11 Q They may not necessarily run all those  
12 tests on every sample, right?

13 A Correct.

14 Q Okay. Have you ever seen a 484 sample  
15 from FDA of Digitek which found that the product was not  
16 within specifications?

17 A I did not.

18 Q Do you know if any exist?

19 A I do not.

20 Q Do you know if the plaintiffs' lawyers who  
21 retained you as an expert in this case ever ran a  
22 Freedom of Information Act request to find out that kind  
23 of information?

24 A I know that there were I believe 1,880  
25 samples taken over a period of time. And my --

1 MR. KERENSKY: No, no. The question is  
2 whether or not you know if the lawyers  
3 representing the plaintiffs --

4 MR. ERNST: Objection, vague. Objection  
5 to form.

6 MR. KERENSKY: -- made a Freedom of  
7 Information Act -- listen to the question.

8 MR. MORIARTY: This is great. Don,  
9 you're objecting to your own side's question. I  
10 love it.

11 MR. KERENSKY: No. I'm just trying to  
12 help him.

13 He's asking you do you know did the  
14 lawyers make a Freedom of Information request, yes  
15 or no. That's what he asked you.

16 THE WITNESS: Is that what you asked me?

17 BY MR. MORIARTY:

18 Q Yes, that's what I asked you.

19 A That did the lawyers for the plaintiffs  
20 ever -- say again, please.

21 Q Do you know whether the lawyers for the  
22 plaintiffs, the lawyers who hired you as an expert in  
23 this case, made a Freedom of Information Act request to  
24 get 484 sampled?

25 A I do not know that.

1 Q Okay. So to the best of your knowledge  
2 FDA never found any out-of-spec Digitek in the field in  
3 its 484 program testing?

4 A To the best -- I don't know the answer. I  
5 don't know if they did or didn't. I believe that --  
6 that's all for that answer.

7 Q Would it be important for you to know  
8 that?

9 A It would be important for me to know if  
10 they sampled a couple hundred thousand and found every  
11 one in specification. That would be important for me to  
12 know and to change the opinion that I have formed.

13 These samples don't tell me statistical  
14 representation that there is not a likelihood of harm  
15 from Digitek -- was not a likelihood of harm from  
16 Digitek out there.

17 Q Okay. Let's talk about scientific data  
18 available to you. Okay?

19 A Yes.

20 Q FDA is your former employer, correct?

21 A Yes.

22 Q You're relying on their 483s and their  
23 warning letters for your opinions in this case about  
24 adulteration, aren't you?

25 A Yes.

1 Q FDA chooses the sample size for their 484  
2 program, don't they?

3 A Yes.

4 Q They can take as many samples as they  
5 want, couldn't they?

6 A Yes.

7 Q So do you have any data anywhere, any  
8 scientific data, that shows out-of-specification Digitek  
9 in the hands of pharmacists or consumers?

10 A I don't have scientific data. However,  
11 the purpose of a surveillance, also known as survey  
12 sample, is to take a sample not indicative of everything  
13 that was produced, but a sample to determine if that  
14 sample is good or not. It does not tell me that there  
15 isn't any harmful Digitek out there. All of this is  
16 small.

17 Q That's nice. What I'm asking you,  
18 Mr. Farley, what data do you have that there is in fact  
19 harmful out-of-specification Digitek out there in the  
20 hands of consumers? Okay? This is what I've got plus  
21 more.

22 A Yes.

23 Q What have you got?

24 A If you mean other than the 483s saying it  
25 was not made right, you mean analytical data showing

1 that something was double strength?

2 Q Let's start there. Do you have any  
3 analytical data?

4 A I do not have analytical data indicating  
5 that.

6 Q Do you have physical measurements from  
7 pharmacists or any reliable scientific person?

8 MR. ERNST: Objection to form.

9 A Of a tablet?

10 Q Of any tablets that were out of spec.

11 A What I read in here that there were at  
12 least 20 of them that were double thickness and they  
13 never analyzed them to see if they were double strength.  
14 But not from a pharmacist I contacted.

15 Q Did any of those 20 double strength  
16 tablets or double thick tablets, whatever you want to  
17 call them, even leave the Actavis facility?

18 A The one that was found by someone at a  
19 nursing home obviously did.

20 Q In 2006?

21 A I believe that's the year.

22 Q I'm asking about the 20 in Batch 70924.  
23 They were removed and destroyed, weren't they?

24 A They were, but it leads me to wonder how  
25 many weren't caught and got out to the consumer.

1 Q You can --

2 A It doesn't tell me it never happened, that  
3 nothing got out.

4 Q You can wonder about that. I'm asking for  
5 your data that it happened. Do you have any data?

6 A No concrete data that it happened.

7 Q All right. So of all the lawsuits and all  
8 the lawyers in the Digitek litigation, did any of them  
9 send you either a double thick tablet or a report that  
10 there was a double thick tablet?

11 MR. ERNST: Objection.

12 A The data that I received from Pete Miller  
13 and all the documents had contained in it the finding of  
14 the double thick tablets. So is that what you -- so my  
15 answer would be yes based on that.

16 Q Okay. I want you to go in the corner and  
17 get your material and I want you to find any piece of  
18 paper in there that says that there was a double thick  
19 tablet in the hands of a consumer in 2006, '7 or '8.

20 A No, not in the hands of a consumer.

21 Q How about in the hands of a pharmacist in  
22 2006, '7 or '8, can you find a piece of paper that says  
23 that?

24 A I cannot find a -- I do not have a paper  
25 that says that.

1 Q Had you ever seen Exhibit 25 before?

2 A I believe not.

3 Q Had you ever seen Exhibit 26 before?

4 A I'd have to check my list of exhibits, but  
5 I believe I did not see these.

6 Q How about 27?

7 A And so on right through the list.

8 Q What about 27?

9 A No.

10 Q What about 28?

11 A No.

12 Q 29?

13 A No.

14 Q 30?

15 A No.

16 Q 31?

17 A No.

18 Q 32?

19 A No.

20 Q 33?

21 A No.

22 Q Or 34?

23 A No.

24 Q In your consultation work is this the kind  
25 of data that you rely on, these 484s, is this the kind



1 of data that you rely on in your consulting work?

2 A To do what?

3 Q To talk to your own clients.

4 A To advise them on how to make good  
5 material?

6 Q Okay. Let me go back, because my question  
7 was bad. Have you ever been consulted by a  
8 pharmaceutical company that the question posed to you  
9 was, do we have any out-of-specification product in the  
10 marketplace?

11 A In the marketplace?

12 Q Yeah.

13 A No, not worded that way.

14 Q Okay. If a client consulted you and  
15 wanted help from you in regard to figuring out whether  
16 there was out-of-specification product in the  
17 marketplace, okay --

18 A Yes.

19 Q -- is the 484 results something that would  
20 be important for you to look at?

21 A They would be part of the picture, not  
22 all.

23 Q Do you know who or what Celsis  
24 Laboratories is?

25 A Could you spell that, please?

1 Q I believe it's C-E-L-S-I-S.

2 A No, not offhand. It might be, but it's  
3 not ringing a bell offhand.

4 Q All right. Are you aware that Actavis  
5 sold all the Digitek it made to distributors, not  
6 directly to pharmacists, in other words?

7 A That's what is normally done. So it  
8 doesn't surprise me.

9 Q And do you know for a fact whether the  
10 distributors like Mylan or UDL commissioned any testing  
11 on the Digitek that it bought from Actavis?

12 A Do I know that they did? I know -- I  
13 would recommend that they should in any case from  
14 anybody. But whether they did, I am not sure offhand.

15 Q Okay. I'm going to hand you Exhibit 35.  
16 First of all, have you ever seen that document before?

17 A I have not.

18 Q Why don't you take a quick look through  
19 it. I'll represent to you that this document contains  
20 information on three Digitek batches made in 2006.

21 These tests were commissioned by Mylan or UDL and the  
22 testing was done by Celsis Analytical Services. Okay?

23 A I see.

24 Q And I believe they did assay and  
25 dissolution testing on these three Digitek batches and

1 found them all to be within the specs. Okay? So take  
2 your time, take a look at that stuff if you'd like and  
3 tell me if I am incorrect in the way I've represented  
4 this exhibit to you.

5 A I hear what you said, but I'm just looking  
6 through it.

7 Q Have you had a chance to go through that?

8 A I'm glancing through some of it. I'm  
9 showing you how far I am. Do you want me to go through  
10 the whole thing?

11 Q All I want you to -- I mean, is that  
12 Celsis Labs results from testing three batches of  
13 Digitek and did they all conform with the specs? That's  
14 the question.

15 MR. KERENSKY: Object to the form of the  
16 question. They didn't test three batches. They  
17 tested three bottles, one bottle each from each  
18 batch.

19 Q Mr. Kerensky is correct.

20 A I heard two questions. Is there  
21 analytical data from Celsis Labs? Yes. Did they test  
22 three --

23 Q Three samples.

24 A Samples.

25 Q Or samples from three batches of Digitek.

1           A    I'm checking that now. It's taking time.  
2   They've got cross-outs on here. I mean, this is not a  
3   good analytical sheet. The numbers are good. But if I  
4   were training an analytical chemist I'd say you don't  
5   cross the number out and not put your initials and the  
6   date on there. That's what I'm looking at right there.

7           Q    Regardless of whether you like Celsis  
8   Analytical Labs' methods, did the three samples pass?

9           A    It was just distracting to me. But the  
10   three samples, samples, passed, yes.

11          Q    Okay. Had you ever seen that document  
12   before?

13          A    No.

14          Q    Here's Exhibit 69. Have you ever seen  
15   this before?

16          A    I'm only on the first page, but my answer  
17   is no.

18          Q    Okay. I will represent to you that  
19   Exhibit 69 represents UDL documents concerning the  
20   testing of Digitek Lot 80111A and that it passed the  
21   tests to which it was subjected. Am I correct?

22          A    This .25 milligram dose, yes, you are  
23   correct.

24          Q    All right. I'm showing you Exhibit 70.  
25   Have you ever seen that before?

1 A I believe I have not seen that before.

2 Q I will represent to you that that's UDL  
3 documents about the testing of Digitek Lot 71034A and  
4 that the samples passed the test to which they subjected  
5 it. Am I correct?

6 MR. KERENSKY: You read 71034A and there  
7 appears to be a 1 after the A.

8 MR. MORIARTY: Correct.

9 MR. KERENSKY: You didn't say the 1.

10 Q Okay. Well --

11 A I heard your question. I'm looking up the  
12 data to tell you if they did pass. Yes, they do pass.  
13 The sample passed.

14 Q I'm handing you Exhibit 71. Have you ever  
15 seen it before?

16 A I believe not.

17 Q I will represent to you that Exhibit 71 is  
18 the UDL documents concerning their testing of Digitek  
19 Batch 71004A1 and that the Digitek passed all the tests  
20 to which they subjected it. Am I correct?

21 A Yes. I'm looking at what tests were done.  
22 That's why I'm pausing. Yes.

23 Q I'm showing you Exhibit 72. Have you ever  
24 seen that document?

25 A I believe I have not.

1                   Q    I will represent to you that it is UDL's  
2 documents regarding the testing of Digitek Lot 70175A1  
3 and that the Digitek passed the tests that they -- to  
4 which they subjected it. Am I correct?

5                   A    I'm looking. Yes, you are correct.

6                   Q    Okay. Now, are you aware that UDL, one of  
7 the things that they did was to re-package Digitek from  
8 bottles to blister packs?

9                   A    I was not aware it was UDL who did that.

10                  Q    But you know it happened at some  
11 distributor level?

12                  A    Yes.

13                  Q    And do you know for a fact from any  
14 documents you've reviewed or any depositions you've read  
15 whether tablets that were double their intended  
16 thickness would have fit into UDL blister packs for  
17 Digitek?

18                  A    I don't know the answer as to whether they  
19 would or would not.

20                  Q    Would it be important for you to know the  
21 answer to that question?

22                  A    I believe it would certainly be, yes, nice  
23 to know.

24                  Q    Because if UDL never rejected any Digitek  
25 tablets as double thick, that would be some scientific

1 information about consistency of the thickness of the  
2 product, correct?

3 A It would. I would have to see their  
4 records as to whether they rejected any. I would have  
5 to see their method of packaging to determine if -- what  
6 system they used to reject anything that was too large  
7 or too small.

8 Q Do you know whether the UDL thickness  
9 specifications for the product were even tighter than  
10 the Actavis specifications?

11 A I don't know that.

12 THE VIDEOGRAPHER: It's time to make a  
13 tape change, sir.

14 MR. MORIARTY: I'm sorry?

15 THE VIDEOGRAPHER: I have to make a tape  
16 change. We are off record at 11:28. Just one  
17 moment. Pause, please.

18 (Off the record.)

19 THE VIDEOGRAPHER: All right. We're back  
20 on record. This is the beginning of Tape No. 3 in  
21 the Farley deposition.

22 BY MR. MORIARTY:

23 Q From your knowledge of the way that FDA  
24 looks at things, if UDL re-packaged Digitek from bottles  
25 to blister packs, would UDL be required to test for

1 stability on the product in order to assure that the  
2 change in packaging didn't change the shelf life of the  
3 drug?

4 A If you have a contact surface area of the  
5 plastic to use to generate current against there,  
6 somebody would be required to test for stability because  
7 of the contact with the drug product.

8 Q Have you ever seen any records from UDL  
9 regarding the results of stability testing for Digitek?

10 A No.

11 Q When they test for stability do they test  
12 for assay typically?

13 A Among others, but that would definitely be  
14 it.

15 Q Would they typically do content  
16 uniformity? Or I'm sorry. Let me withdraw that.

17 Would they typically also do dissolution?

18 A For tablets would they typically?  
19 Usually, not invariably, but most times. Typically was  
20 your word. Let's use that. Yes.

21 Q To your knowledge did any Digitek batch  
22 ever fail stability under any UDL program?

23 A I don't know the answer to that.

24 Q Would that be important information for  
25 you to know?



1 A It would be.

2 Q And if you assume that no Digitek batch  
3 ever failed stability under a UDL program, does that  
4 speak to the consistency of the quality of the product?

5 A If I saw the stability protocol and if I  
6 saw the method they used and agreed that it was a good  
7 method and if I knew it was a well-trained person  
8 conducting it, everything that would give credibility to  
9 the results, then, yes, it would.

10 Q And no one has submitted any of that kind  
11 of data to you for review in this litigation, correct?

12 A I believe they did not.

13 Q And you have no reason to believe that FDA  
14 has questioned the testing methods of UDL, correct?

15 A Correct.

16 Q If -- have you been supplied any  
17 information about testing on Digitek done by NMS Labs  
18 from your previous home area of Philadelphia?

19 A No.

20 Q Are you familiar with NMS Labs?

21 A No.

22 Q If anybody ever presented you with testing  
23 information about Digitek would you want to look at  
24 their methodology and validation before you drew any  
25 conclusions about the validity of the testing?

1           A     That and more. The reputation of the  
2     company, something about the training of the analysts  
3     who were running it. Everything you said and more.

4           Q     Okay. Now, my colleague, Mr. Anderton,  
5     already asked you some questions about the regulatory  
6     definition of adulteration. And I don't want to repeat  
7     those questions, but I have a follow-up.

8                     Have you ever seen any peer reviewed  
9     scientific literature, any FDA statements or any other  
10    kind of scientific statement which says in words or  
11    effect that the regulatory definition of adulteration  
12    means that there was out-of-specification product in  
13    fact either made or distributed?

14          A     You're getting to like within the  
15    definition of adulteration? Is that -- am I reading  
16    your question properly or am I not?

17                     MR. ERNST: Objection to form.

18          Q     I thought the question was plain. If you  
19    don't understand it I'll be happy to rephrase it.

20          A     Okay. Just one more time. Let me see if  
21    I get it this time.

22          Q     Okay. All right. Let me go back. All  
23    right. Mr. Anderton asked you about Exhibit 39. Okay?

24          A     I forget what one that is offhand but --

25          Q     I'm handing you from the original stack

1 what Exhibit 39 is. Okay?

2 A Yes. I see it.

3 Q And this is the statement from the FDA's  
4 own Web site, Facts About Current Good Manufacturing  
5 Practices, correct?

6 A It looks like it is.

7 Q And about halfway down there's a bolded  
8 question that says, If a manufacturer is not following  
9 CGMPs are drug products safe for use.

10 Do you see that?

11 A Yes.

12 Q And then it basically gives the statement  
13 that if a company is not complying with CGMPs it makes  
14 the drug adulterated under the law.

15 Do you see that?

16 A Yes.

17 Q The last sentence of that paragraph says,  
18 It does not mean that there is necessarily something  
19 wrong with the drug.

20 Do you see that?

21 A Yes.

22 Q Okay. Now, what I want to know from you  
23 is whether you have any peer reviewed literature or an  
24 FDA statement or some other scientific statement  
25 contrary to what the FDA is saying in its Web site in

1 Exhibit 39.

2 A Stating --

3 Q First a yes or no and then you can  
4 explain.

5 A Do I have any evidence of anyone who  
6 directly contradicts that?

7 Q That's basically what I was asking you.

8 A I do not.

9 Q Okay. Now, did you want to explain your  
10 answer?

11 A Yes.

12 Q Go ahead.

13 A When there's a violation of GMPs it is  
14 implied or understood in the industry or generally  
15 accepted there is a likelihood that an improper  
16 harmful -- potentially harmful product is being released  
17 to the public.

18 It, as you say, is not a guarantee, but  
19 there's a likelihood that there's a, quote, bad product  
20 getting out to the market if in fact it was released.

21 So while there's no direct contradiction here  
22 as you asked, it's the general thinking among people in  
23 the industry and FDA you didn't comply with GMPs,  
24 there's a likelihood of a problem with this material.

25 Q Okay. Let me ask you about that. Does

1 every finding of adulteration lead to a recall?

2 A No.

3 Q Well, if you are correct that there is a  
4 likelihood that bad product is out, how come it isn't  
5 recalled?

6 A It's a combination of factors. It depends  
7 on the product itself. If it's a drug, how sensitive is  
8 that drug. In this case it's therapeutic index. A  
9 person might get harmed. It's who's taking it. There's  
10 a whole variety of factors that go into the  
11 determination to do a recall or not.

12 Q But you told me that every time there's an  
13 adulteration there's a likelihood that bad product got  
14 out. Okay? So where in the FDA rules, regs,  
15 interpretations, field manuals does it give this sort of  
16 rule that you just said that there's a likelihood but it  
17 all depends? Where is it?

18 A In the regulations where it says there's a  
19 likelihood?

20 Q Yeah. Where in the regs, where in a piece  
21 of scientific peer reviewed literature, where in a  
22 manual anywhere that I can go read to check on what you  
23 just told me?

24 A It says it's an adulterated product.  
25 Since it's an adulterated product it has not been made

1 the way it should have been made and will quite likely,  
2 quite likely, not be of the identity, strength, quality  
3 and purity they say that it is purported to be and in --  
4 it could be harmful.

5 Q Well, does the definition of adulteration  
6 in the regulations say that? Does it use the word  
7 likely?

8 A I read it somewhere and I'm at a loss to  
9 quote it now. I don't know if I read it in the  
10 regulations or some document but -- or whether I heard  
11 it at meetings at the FDA. I don't know.

12 Q I'm asking you a question of whether the  
13 regulation itself that defines adulteration --

14 A Yes.

15 Q -- uses the word likely.

16 A I do not know if it does or doesn't  
17 offhand. I would have to read that regulation. I'm not  
18 saying it does; I'm not saying it doesn't. I just don't  
19 know.

20 Q So let me get back to my basic question.  
21 Can you cite for me a piece of peer reviewed literature,  
22 a regulation, a manual, any piece of scientific  
23 information that indicates that adulteration means that  
24 there is a likelihood that bad product actually made it  
25 to the market?

1 MR. ERNST: Objection to form.

2 A It means by definition --

3 Q Wait. Answer my question, please, and  
4 then you can give your explanation.

5 MR. ERNST: Objection to form. You  
6 haven't asked a question.

7 A I thought I was trying to answer your  
8 question. Can I try that again to see --

9 Q Sure.

10 A It means you didn't make it the way you  
11 said you would make it, and therefore, it is not exactly  
12 what you said it would be.

13 Q Isn't it in fact just possible that it's  
14 not what you said it would be?

15 MR. ERNST: Objection to form.

16 A The way we would think when I was at FDA,  
17 the thinking that's engrained into you is, you didn't  
18 make it the way you said, therefore it isn't what you  
19 want it to be.

20 Q Okay. I'm asking you, but isn't it just  
21 possible that it's not what you want it to be as opposed  
22 to likely?

23 MR. ERNST: Objection to form.

24 A Getting into possible, likely, probable,  
25 that depends on who you ask.

1 Q I'm asking you under oath today as an  
2 expert in the Digitek litigation. Okay? You can't  
3 point me to anything in the regs or any other scientific  
4 writings that support what you're saying.

5 So I'm asking, isn't it in -- a fact that when  
6 there is an adulteration by definition under the FDCA,  
7 that it only means it's possible that bad product  
8 actually got out?

9 MR. ERNST: Objection to form.

10 A Now, if you're asking me how I would feel  
11 about it, if you put a medication in front of me like  
12 Lipitor that I take and said this is a -- this is a  
13 generic firm made this, but it wasn't made according to  
14 GMPs, take it, Jim, and save a few bucks, I would say, I  
15 don't want to take that, because in my mind there's a  
16 likelihood that something is wrong with that.

17 Q So that's your personal opinion?

18 A That's -- that's the opinion I just gave.  
19 I wouldn't take it if someone said this is -- this would  
20 save you a couple bucks, but it's not made according to  
21 GMPs. I wouldn't.

22 Q Okay. So that's why in your article that  
23 we asked you about before you actually want to test it  
24 to see if it is or isn't, right?

25 A I would want to test it to see the final



1 product, assay, everything. But I also want to know  
2 it's made according to GMPs.

3 Q Well, that's -- anything in Exhibit 39 in  
4 the FDA's own Web site that says that it's likely that  
5 the product that got out was in fact bad?

6 A I don't see the word likely.

7 MR. ERNST: Form.

8 Q Did your co-author, Mr. Brooks, in your  
9 article that you guys wrote cite any law or regulations  
10 to say that it's likely that defective product is out  
11 there when it's adulterated?

12 A I don't actually remember whether we did  
13 or not. I don't. It was over two years ago we wrote  
14 that.

15 Q Okay.

16 MR. MORIARTY: Does it smell to anyone  
17 else in here like there is something burning?

18 THE VIDEOGRAPHER: Do you want to go off  
19 record?

20 MR. MORIARTY: Yeah.

21 THE VIDEOGRAPHER: We're off record. The  
22 time is 11:44.

23 (A brief recess was taken.)

24 THE VIDEOGRAPHER: We're back on record,  
25 11:44.

1 MR. MORIARTY: Okay. Let's go back on  
2 the record.

3 BY MR. MORIARTY:

4 Q Have you ever seen any Actavis documents  
5 from either blend uniformity testing or finished product  
6 testing that show out-of-specification results for  
7 Digitek?

8 A Out-of-specification with regard to double  
9 thickness?

10 Q Or normal size, too much API, other than  
11 the 20 tablets in 70924.

12 A Other than that?

13 Q Yeah.

14 A I was going to say what I've seen is those  
15 documents and I didn't --

16 Q And the assays?

17 A -- see those results on them. I have not  
18 seen anything since then.

19 Q Okay. Let's go back to this statement  
20 about likelihood or not likelihood. Okay? This goes  
21 here. This is Exhibit 38. It's another statement from  
22 the FDA's Web site called Facts and Myths About Generic  
23 Drugs.

24 A I see it.

25 Q On the second page near the top it says

1 Myth, There are quality problems with generic drug  
2 manufacturing. A recent recall of generic Digoxin,  
3 called Digitek, shows that generic drugs put patients at  
4 risk.

5 And then it says Fact, FDA's aggressive action  
6 in this case demonstrates the high standards to which  
7 all prescription drugs, generic and brand name, are  
8 held.

9 Do you see that?

10 A I do.

11 Q All right. In the fourth bullet point it  
12 says, In our best judgment given the very small number  
13 of defective tablets that may have reached the market  
14 and the lack of reported adverse events before the  
15 recall, harm to patients was very unlikely.

16 Do you see that?

17 A The fourth bullet point?

18 Q Yes, sir.

19 A I see it but I'm questioning the FDA  
20 putting that on their Web site. I'm not doubting what  
21 you put in front of me, but I'm questioning their  
22 mentality when they put that out there, because they  
23 don't usually get specific.

24 And I think when Mr. Anderton presented this I  
25 said the same thing. I said they don't usually go into

1 brand names. And it's very much of a surprise. But,  
2 yes, I see what you put in front of me.

3 Q All right. Other than 483s and warning  
4 letters what documents have you seen to indicate that it  
5 is likely that there was defective Digitek in the hands  
6 of any consumer?

7 A Consent decree.

8 Q Anything else?

9 A A consent decree is a big deal. That's a  
10 big --

11 Q Can consent decree say -- even have the  
12 word Digitek in it?

13 A It essentially said, my words, we don't  
14 think you're capable of making anything right;  
15 therefore, you need a third party to help you make it.

16 Q Okay. So you've seen all this Celsis Labs  
17 testing.

18 A No.

19 Q You've seen the FDA's testing.

20 A This morning.

21 Q And you haven't even looked at any Actavis  
22 batch records other than 70924. So other than the FDA's  
23 regulatory documents what have you seen to indicate to  
24 you that there is any likelihood of out-of-spec Digitek  
25 in the hands of any consumer?

1           A    It sounds to me like you're minimizing the  
2   significance of a 483 or a warning letter.

3           Q    No, sir.

4           A    They are serious things.

5           Q    What I'm trying to ask you -- I'm trying  
6   to understand your opinions and the support for your  
7   opinions.

8           A    Yes.

9           Q    I understand what you relied on, those  
10   three categories. I want to know if there's anything  
11   else. Okay? You've said warning letters, 483s and a  
12   consent decree. Anything else?

13          A    And the double thick tablets that were  
14   found and not analyzed, which is surprising.

15          Q    I'm -- maybe you're missing the question.

16          A    I might be.

17          Q    Okay? I want to know any documents that  
18   indicate to you the likelihood that out-of-spec Digitek  
19   made it to the hands of consumers, okay, hands of  
20   consumers, not rejected at the plant.

21          A    Separate from my feeling that there was a  
22   good possibility that some might, I haven't seen a  
23   document that indicated that there was. But what I'm  
24   looking at is not the quantity.

25                You could show me a hundred more analytical

1 results of a bottle here and a bottle there. But when I  
2 take the few 483s and couple of warning letters and I  
3 look at what was wrong with that place, I realized the  
4 sampling was a very small amount. And I would not have  
5 confidence in taking any medication that they produced.

6 Q Okay.

7 A So that's a lengthy answer, but I want to  
8 put it in a proper perspective for all of us.

9 Q If a client hired you to analyze this, you  
10 would look at the actual records, the manufacturing  
11 records, the testing records, things of that nature.  
12 You would actually want the detail, not just the  
13 broadbrush of the 483s, correct?

14 A Including the methods and the training,  
15 all of the above.

16 Q All right. Did you review any annual data  
17 reviews or annual reports?

18 A I did not. I believe I did not.

19 Q Do you know that has summaries of all of  
20 the testing, finished product testing --

21 A Yes.

22 Q -- for every batch?

23 A Yes.

24 Q Now, the ANDA -- you know what that is,  
25 right --

1                   A     It's the Abbreviated New Drug Application  
2     for generic.

3                   Q     -- contains a -- have you seen the ANDA  
4     for Digitek?

5                   A     The actual ANDA?

6                   Q     Yeah.

7                   A     No.

8                   Q     I mean, a copy of it?

9                   A     No.

10                  Q     Well, you know that the ANDA has a product  
11     formula, does it not?

12                  A     Yes.

13                  Q     It lists the ingredients and the amount of  
14     an ingredient?

15                  A     Yes.

16                  Q     And you know that formula was approved by  
17     FDA?

18                  A     Yes.

19                  Q     And do you know typically in the  
20     manufacturing process that raw materials, including the  
21     API, are weighed at the beginning of each batch to  
22     assure that the proper amount is put in that complies  
23     with the formula?

24                  A     Yes.

25                  Q     Do you know that from review of any batch

1 records that when they are blended one person verifies  
2 it and it's verified by a second person that the  
3 blending is done properly?

4 A Yes. I only reviewed the one batch record  
5 and in that one I found that the same person checked his  
6 or her own work, which is sacrilegious, one might say.

7 Q In the blend?

8 A In -- somewhere along the way. I forget  
9 offhand. I'd have to review the batch record again to  
10 answer that. But I found -- in effect I'm saying I  
11 found a flaw in it and that flaw was a person checking  
12 his or her own work, same initials on the left side and  
13 right side of the sheet, which is a violation right  
14 there.

15 Q Have you seen any citations, warnings or  
16 sanctions from the FDA upon Actavis for not following  
17 the Digitek formula that was set out in the ANDA?

18 A No.

19 Q Did Actavis keep raw material inventory  
20 cards?

21 A I do not know that. They should. They're  
22 supposed to.

23 Q Have you ever seen anything to indicate  
24 that Actavis was using Digitek components at rates  
25 inconsistent with their batch production?



1                   A    No.  I saw they were not cleaning the  
2   materials properly, the equipment, between batches,  
3   which cause concern.  But your question referred to the  
4   proper amounts, I believe, and my answer is no.

5                   Q    My questions are relatively specific and  
6   direct.

7                   A    Okay.

8                   Q    If you can just answer mine --

9                   A    Okay.

10                  Q    -- not some other.  I didn't ask you about  
11   cleaning validation or anything else.

12                  A    Yes.

13                  Q    I asked about inventory.

14                  A    Yes.

15                  Q    Okay?  Have you ever seen evidence of an  
16   FDA citation, warning or observation that Actavis was  
17   using too much Digoxin as tested at the blend uniformity  
18   stage?

19                  A    No.

20                  Q    Do you know that periodically tablets are  
21   tested by QA and production during manufacturing for  
22   hardness, thickness and weight?

23                  A    Yes.

24                  Q    Do you know that those sampling plans were  
25   approved by the FDA?

1           A    I didn't see them, but I would have to  
2   assume they were.

3           Q    Have you ever seen any FDA citation,  
4   warning or observation to indicate that Actavis was not  
5   following its FDA approved sampling plans?

6           A    I'm reflecting on the 483s as I'm  
7   formulating my answer. I'm trying to think if sampling  
8   plans were in the 483s. My answer is no.

9           Q    Do you know how many out-of-specification  
10   results occurred of the 270 Digitek batches made between  
11   2003 and 2007 during production for weight, thickness or  
12   hardness?

13          A    I do not know.

14          Q    Now, from a manufacturing and quality  
15   standpoint is there a difference between a double thick  
16   tablet and a normal sized tablet with too much active  
17   pharmaceutical ingredient?

18          A    Is there a difference?

19          Q    Yeah.

20          A    The very fact it's double thick is the  
21   difference. I need a little more information --

22          Q    Sure.

23          A    -- on the question. I'm not getting it.

24          Q    Well, I know you're not a manufacturing  
25   expert. But in fact, is the root cause of a double

1 thick tablet different from the root cause of a normal  
2 sized tablet that has too much active pharmaceutical  
3 ingredient?

4 A It can be.

5 Q Do you think the FDA knows the difference  
6 between a double thick tablet and a normal sized tablet  
7 with too much active pharmaceutical ingredient?

8 A They should.

9 Q Did you ever see any citations, warnings  
10 or observations to indicate that Actavis was  
11 manufacturing Digitek normal size but too much active  
12 pharmaceutical ingredient?

13 A I did not see much analytical data at all  
14 and I did not see anything to that effect.

15 Q I'm not asking you about analytical data.  
16 I'm asking whether you saw any FDA observations,  
17 citations or warnings to indicate that Actavis was  
18 making Digitek normal size but with too much active  
19 pharmaceutical ingredient.

20 A No.

21 Q And the FDA approved recall notice didn't  
22 say anything about normal size tablets with too much  
23 API, did it?

24 A Correct.

25 Q If FDA was concerned about the specific

1 problem of normal sized tablets with too much API, do  
2 you think they would have had Actavis say something  
3 about that in the recall notice?

4 MR. ERNST: Objection to form.

5 A I'm thinking whether they would have  
6 tested it first or got the recall out first. I believe  
7 they would have said something about it, tell the reason  
8 for the recall.

9 Q And they probably would have said  
10 something about it in Exhibit 38 on their Web site when  
11 they specifically talk about Digitek and the recall a  
12 year and a quarter after the recall had occurred,  
13 correct?

14 A I can't predict what they would or would  
15 not because I'm not in agreement with the way they  
16 formulated this in the first place.

17 Q Well, if information had come to the FDA's  
18 attention even post-recall that there was a problem with  
19 normal sized tablets and too much active pharmaceutical  
20 ingredient in them, don't you think they would have said  
21 something in Exhibit 38 about that?

22 A I don't know. I can't predict what they  
23 would or wouldn't put on there. I really can't answer  
24 that. I don't know who can.

25 Q Well, if you worked for the FDA wouldn't

1 you say something about that?

2 A I think the answer to that you'd have to  
3 ask Dr. Margaret Hanburg. She's the commissioner.

4 Q Were the finished product testing plans  
5 approved by FDA?

6 A They should have been.

7 Q Were they in every batch record?

8 A Should have been.

9 Q Did FDA have every opportunity to inspect  
10 and comment upon those testing plans between 2004 and  
11 2008?

12 A I don't know what the inspectors had on  
13 their agendas when they left the office to go and  
14 inspect. I can't speak for that. I'd be happy to read  
15 the minds of the ladies who did the inspections.

16 Q I'm not asking whether they had it on  
17 their agenda, Mr. Farley. I'm asking whether they had  
18 the batch records available for review when they did  
19 their inspections.

20 A They could request the batch records at  
21 any time. So in that regard it would be available for  
22 review if they felt they needed the batch records.

23 Q And if they were suspicious about Actavis'  
24 finished product testing program do you think it likely  
25 that the inspectors would have looked at those?

1           A    About Actavis' finished product testing  
2   program --

3           Q    Yes.

4           A    -- is it likely -- we get into this word  
5   likely. It is possible they may have.

6           Q    No. So you think if FDA was concerned  
7   about Actavis' finished product testing that it's only  
8   possible they would have looked at batch records?

9           A    At that time when that inspection when  
10   they're finding deviations, out-of-specification  
11   results, things not being documented, they had their  
12   hands full with all the other violations.

13           And they might have gone back to the district  
14   and said, I need a couple other people to come with me  
15   next week. I'm assuming you mean that day are they  
16   going to ask for it.

17           Q    No. At some point they would have gotten  
18   to it, right?

19           A    At some point? They may have gotten to it  
20   depending on the personnel -- they had their hands full  
21   with all of the violations in the first place.

22           Q    At some point it's probable they would  
23   have gotten to it, right?

24           A    Possible.

25           Q    Okay. Did FDA ever cite, warn or observe

1 that Actavis was not following its finished product ANDA  
2 procedures for Digitek?

3 A ANDA procedures? Could you explain that  
4 more?

5 Q The ANDA sets forth the finished product  
6 testing procedures, doesn't it?

7 A I didn't hear you say finished product  
8 testing. I'm sorry.

9 Q And it's FDA approved, correct?

10 A Yes.

11 Q Did FDA ever cite, warn or observe that  
12 Actavis was not following its finished product testing  
13 procedures regarding Digitek?

14 A Procedures that Digitek proposed and FDA  
15 said, okay, they're good, do it? No, I did not see  
16 that.

17 Q When we say finished product testing  
18 procedures, we're on the same page. We're talking about  
19 assay, dissolution and content uniformity, correct?

20 A From what I've read here this morning,  
21 finished product testing is testing on the product as it  
22 leaves to go to the next consumer.

23 Q Do you know what kind of testing it is?

24 A I'm sorry. Say again?

25 Q Do you know what kind of testing they do?

1           A    From what I read this morning -- I know  
2   what they should do normally, but I know more  
3   specifically from what you showed me this morning.

4           Q    Well, when you read Batch 70924's records  
5   did you look at the kind of testing Actavis subjected  
6   the product to?

7           A    Yes.

8           Q    And it was assay, dissolution and content  
9   uniformity, correct?

10          A    Yes.

11          Q    Okay. Did FDA ever cite Actavis or  
12   observe that Actavis had out-of-specification stability  
13   results for Digitek?

14          A    They cited them for not taking samples at  
15   the prescribed time that was in their stability  
16   protocol. Therefore, they found a flaw in the program.  
17   So when you have a flaw in the program and then you say  
18   did I have out-of-spec samples, it's a tough one to  
19   answer because you aren't taking all the samples you  
20   were supposed to take.

21          Q    Okay. I'm just asking, did they ever  
22   cite, observe or warn Actavis for out-of-specification  
23   stability samples? Yes or no?

24          A    For out-of-specification stability  
25   samples? No.



1 Q Or content uniformity?

2 A No.

3 MR. MORIARTY: How much time on the tape?

4 THE VIDEOGRAPHER: The time on the tape  
5 left is 25 minutes.

6 MR. MORIARTY: Okay.

7 BY MR. MORIARTY:

8 Q Let me see if I can put a question to you  
9 a different way. You've -- you've seen the 484s.  
10 You've seen the Celsis and UDL testing. I want you to  
11 assume that the batch records for Digitek show  
12 consistent production within the specifications. Okay?

13 A Yes.

14 Q I want you to assume that.

15 A We'll do that.

16 Q All right. Are you -- do you intend to  
17 tell a jury that Actavis was in fact producing defective  
18 Digitek and it's just sheer coincidence that none of  
19 that defective product was discovered by Actavis, FDA,  
20 UDL or Celsis?

21 A I do not intend to tell anybody that  
22 because I don't know that. I was -- I don't have  
23 confidence they're capable of making a quality product  
24 even though they got good analytical results on what is  
25 an extremely small percentage of sampling.

1 But I can't say they made bad stuff. I say in  
2 my mind I believe there's a likelihood, in my mind, a  
3 likelihood that there could be bad material on the  
4 market.

5 Q Okay.

6 A Can I clarify that more for my own mind,  
7 too?

8 Q Now, if you were going to be consulted by  
9 a client for that very problem, okay, somebody says we  
10 think there was adulterated product, but all the testing  
11 that's been done shows that the product is within specs,  
12 what would be your next step to figure out whether there  
13 was in fact bad product in order to remove the doubts  
14 and wonderings?

15 A I would say to them why do you think you  
16 made adulterated product?

17 Q That's not what I'm asking you. You've  
18 been consulted. Okay?

19 A Right.

20 Q We know the FDA has done these 483s and  
21 the warning letters. Okay?

22 A Uh-huh.

23 Q But all the test results show normal  
24 Digitek. No one has come and shown you defective  
25 Digitek. What would be your next step as a consultant

1 to advise the company about whether there was in fact  
2 out-of-specification Digitek out in the market?

3 A I don't think that's the same question you  
4 asked me a minute ago.

5 Q Well, I think -- answer the one I just  
6 asked you.

7 A The question --

8 Q Answer the one I just asked.

9 A Give it to me again, please.

10 MR. MORIARTY: Read it back, Angela,  
11 please.

12 (The record was read back as requested.)

13 A What's the company asking me? I mean,  
14 what's -- I'm missing --

15 Q Mr. Farley, is there defective Digitek in  
16 the hands of consumers?

17 A Oh, your company.

18 Q Yeah. Not is it adulterated. We want to  
19 know, because we've got all these good test results, is  
20 there defective Digitek in the hands of consumers? What  
21 do you do as a consultant?

22 A I want to review all your procedures,  
23 every procedure, your lab testing, your manufacturing.  
24 I want to see existing data. But you've just assured me  
25 existing data was good.

1 I want to verify that the methods were  
2 accurate, validated and that the personnel are trained.  
3 And then I want to look -- I want to watch you make a  
4 batch. I want to watch you test it.

5 Q Did FDA ever cite, warn or observe that  
6 Actavis didn't have validated methods for the production  
7 and testing of Digitek?

8 A They said they weren't using certain  
9 methods, that methods that were supposed to be used were  
10 not being used. Whether they cited for any being not  
11 validated, I'm not sure. There may have been. I'm just  
12 not sure. But I do know they said you had procedures,  
13 you weren't using them.

14 Q Any that specifically involved the actual  
15 quality of the end product?

16 A Anything in manufacturing involves quality  
17 of the end product. So my answer is yes.

18 Q Okay. So in your mind if somebody put a  
19 label on upside down -- which would be a GMP violation,  
20 wouldn't it --

21 A Yes.

22 Q -- that is -- that means it's likely that  
23 that product is out of specification?

24 A It means you don't know anything about  
25 that product. It means what are you going to do about

1 it. You've got to take that product, that big drum or  
2 whatever it is, and test it to be sure that what you  
3 think it is is really what it is.

4 Q Okay.

5 A You can't --

6 Q Well, it passed finished product testing,  
7 Mr. Farley. So are you telling me that in your mind the  
8 upside down label means that that product is out of  
9 specification?

10 A No. It means they're -- it means you have  
11 to look more into it. There's a possibility it may be.  
12 Upside down label, you don't know what's there.  
13 Whatever the label says, you don't know what's in that  
14 drum.

15 So you have to do a tracking of how whatever  
16 it is got there, plus you've got to do some more testing  
17 here and now before you do anything with that.

18 Q Okay. Did FDA ever cite, warn or observe  
19 that Actavis employees were not properly trained in  
20 manufacture of Digitek?

21 A I did not read anything to that effect.

22 Q If the -- if Actavis was consistently  
23 producing double thick tablets, is it more likely than  
24 not that it would have been detected either by  
25 pharmacists filling prescriptions, consumers taking

1 prescriptions or UDL when it was packaging the product  
2 in blister packs?

3 A Consistently, that's a somewhat vague  
4 term. But if you mean daily with batches that go out,  
5 it is likely that someone somewhere would have caught  
6 it. It's also likely that some people would have  
7 ingested it and either died or had some serious medical  
8 problems.

9 Q All I'm asking you is whether it's likely  
10 it would have been detected and that is the look,  
11 correct?

12 A Oh. I was just saying before or after the  
13 fact. It's likely it would have been defected. When I  
14 don't know.

15 Q All right. Do you know -- do you know how  
16 many -- do you know how many Digitek tablets were  
17 recalled?

18 A A figure -- or not -- no. 4.8 million,  
19 that's a batch. Many, many millions. I don't know the  
20 exact number offhand.

21 Q Okay.

22 A Tablets you're talking about?

23 Q Yeah.

24 A Okay. Many, many millions.

25 Q Like 688 million?

1 A That wouldn't surprise me.

2 Q Do you know how many of the recalled  
3 batches were .125 versus .250?

4 A Not offhand.

5 Q Do you know what percentage -- do you have  
6 an opinion to a probability what percentage of the  
7 recalled Digitek was defective by being out of  
8 specification low?

9 A Out of specification low?

10 Q Yes.

11 A I do not --

12 MR. ERNST: Objection to form.

13 A -- have any knowledge to that effect.

14 Q Do you have an opinion to a probability?

15 A No.

16 Q Do you have an opinion to a reasonable  
17 degree of probability as to what percentage of the  
18 recalled Digitek was defective by being out of  
19 specification on the high side of the API?

20 MR. ERNST: Objection to form.

21 A No, I don't have an opinion or any  
22 knowledge of that.

23 Q If there were out-of-specification Digitek  
24 with the API on the high side, above its specifications,  
25 do you have any opinion to a probability as to how high

1 those were?

2 MR. ERNST: Objection to form.

3 A If they were out on the high side do I  
4 have an opinion how high they would be?

5 Q Yep.

6 A No.

7 Q Do you have an opinion as to how many  
8 double thick tablets were released to the marketplace  
9 between 2006 and 2008?

10 A I do not.

11 Q Do you have an opinion to a reasonable  
12 probability as to how many normal sized tablets with too  
13 much API were released to the market?

14 A I do not.

15 Q Given what you have told me so far I  
16 assume you have no opinion to a probability as to how  
17 many out-of-specification tablets may have made it into  
18 a particular patient's prescription vial, whether they  
19 got one or whether they got none, whether some people  
20 got tend out of thirty.

21 Do you have any opinions to a probability on  
22 that?

23 A No opinion as to a probability.

24 MR. MORIARTY: How we doing on time,  
25 Bill?



1 THE VIDEOGRAPHER: We have thirteen  
2 minutes, sir.

3 MR. MORIARTY: Okay.

4 BY MR. MORIARTY:

5 Q All right. Flipping through notes, some  
6 of these I've already asked you, so -- I think you said  
7 in your first deposition you said something about  
8 somebody dying from Digitek eight to ten years before  
9 the recall.

10 Do you know where you got that information?

11 A I mentioned something that I had heard or  
12 read that a person had died. And I think it was  
13 Mr. Anderton who put it in the proper perspective and  
14 mentioned when.

15 The other part of your question was where did  
16 I get that. I am not sure. It might have been Pete  
17 Miller telling me or in a conversation. But it was  
18 something like that.

19 Q Do you have any scientific basis to know  
20 whether people taking normal doses of Digoxin can have  
21 toxicity and die as a result?

22 A No. That would be more for an M.D. and  
23 I'm not a physician.

24 Q And you haven't read the depositions of  
25 Dr. Semigran or Ph.D. Nelson from Cincinnati in this

1 litigation?

2 A No, neither of them.

3 Q So you don't know whether that came from  
4 an adverse event report that was in your material or  
5 some anecdotal piece of information?

6 A I don't know that -- what was in the  
7 adverse --

8 Q This thing about somebody dying eight to  
9 ten years before.

10 A I don't know.

11 Q Okay. Are you an expert in statistics?

12 A No, I'm not an expert in statistics. I  
13 know a little bit, but not an expert.

14 Q Do you know what level of testing of a  
15 product would rise to the level of statistical  
16 significance or would you defer to a statistician on  
17 that?

18 A I would defer to a -- I would have an  
19 idea, but I would defer to a statistician to look for  
20 the traditional 95 percent probability of this occurring  
21 rather than that.

22 Q Okay. Now, this statement about a total  
23 failure of the quality systems --

24 A Yes.

25 Q -- if somebody were to assume that there

1 was a total failure and that Actavis could not make  
2 Digitek within the specs, that would be an improper  
3 assumption, wouldn't it?

4 A I'm trying to think if it's the same that  
5 my thoughts are. I wouldn't trust anything they made  
6 after seeing that. But to say that a particular bottle  
7 is good or bad, I would have no way of knowing.

8 Q Okay.

9 A Did I answer your question?

10 Q Well, not exactly but I'm going to follow  
11 up.

12 A Okay.

13 Q If somebody said there was a total failure  
14 of the quality system, so we assume that Digitek could  
15 not have been made properly, that would be a wrong  
16 assumption, wouldn't it?

17 A If somebody said there was a total  
18 failure --

19 Q Yes.

20 A -- and --

21 Q And then assumed that Actavis could not  
22 make any Digitek properly, they would be wrong, wouldn't  
23 they?

24 A Well, if somebody told me there was a  
25 total failure I'd say, tell me why you say that, why are

1 you saying a total failure. Then I would want to hear  
2 all the various reasons that made them use that term.  
3 Then I would pass judgment.

4 Q I'm asking you a simple question. Okay?  
5 If somebody said there's a total failure of the quality  
6 system and then they assumed that Actavis could not make  
7 Digitek within the specs, from what you know and what  
8 you've even seen today that would be a wrong assumption,  
9 wouldn't it?

10 MR. ERNST: Objection.

11 A On the samples that were tested those  
12 samples were good. So it would be an erroneous  
13 assumption to say that everything that came out was bad.

14 Q Okay. Thank you. Now, let me make sure I  
15 understand something you said in your deposition -- your  
16 first session of your deposition. We had 70924 with the  
17 20 double thick tablets, correct?

18 A Yes.

19 Q You remember that?

20 A I remember that.

21 Q And I got the impression from what you've  
22 said earlier that if somebody showed you the preceding  
23 batch and the trailing batch after 70924 and they were  
24 fine and within the specs during production and finished  
25 product testing, that you would consider something like

1 70924 to be an isolated incident.

2 Do I understand that correctly?

3 A I need more batches. No, no, not just the  
4 one before or the one after. Maybe the five or ten  
5 before and the five or ten after.

6 Q Okay.

7 A I need more than just what you said to  
8 have me look at that I say potentially isolated  
9 incident.

10 Q All right. Did you ask for any specific  
11 number of preceding or trailing batches in this case?

12 A I believe my words were something to the  
13 effect of give me whatever you can get before and after.

14 Q And did you get anything other than 70924?

15 A No, sir.

16 Q So as it stands right now you don't know  
17 whether that was an isolated incident. Is that fair?

18 A Whether the findings of the 20 double  
19 thick tablets were isolated?

20 Q Yes, sir.

21 A I do not know if that was or was not an  
22 isolated incident.

23 MR. MORIARTY: Okay. Let's go off the  
24 record. I want to take five minutes with my  
25 colleague to see if I am finished and then she can

1 ask questions if she wants.

2 THE VIDEOGRAPHER: All right. Off

3 record, 12:25 p.m.

4 (A brief recess was taken.)

5 THE VIDEOGRAPHER: We're back on record.

6 This is the beginning of Media Unit No. 4 and it  
7 is 12:49.

8 BY MR. MORIARTY:

9 Q Okay. Mr. Farley, I just have two things  
10 to do. One is housekeeping. Okay? This is  
11 Exhibit 74C. It is the latest version of the notice for  
12 this deposition. Okay?

13 A Yes.

14 Q The first notice of deposition was marked  
15 as an exhibit in your last session. Do you remember  
16 that?

17 A Yes.

18 Q The big difference between this one and  
19 that one basically says that you are to bring with you  
20 all additional documents that you reviewed.

21 A Yes.

22 Q I asked you in the beginning of your  
23 deposition whether you had reviewed additional documents  
24 and you said you had not; is that correct?

25 A Yes.

1 Q All right. So let me ask you my final  
2 question just to make sure that I can understand how you  
3 got to a conclusion. Okay?

4 A Yes.

5 Q If somebody concluded, like you, that  
6 there was likely out-of-specification product in the  
7 marketplace, they could reach that conclusion in one of  
8 two ways. Okay? One is to read the regulatory  
9 documents and reach that conclusion, right?

10 A The 483s?

11 Q Yes.

12 A Yes.

13 Q And that's the way you reached your  
14 conclusion, correct?

15 A Yes.

16 Q Another way would be to read the results  
17 of scientific tests or reports that people had measured  
18 out-of-specification tablet in the field. That would be  
19 a different way to reach that conclusion, correct?

20 A I wouldn't reach the same conclusion.

21 Q I'm not asking whether you reached that  
22 conclusion. That would be another way to reach that  
23 conclusion if in fact that it occurred, right?

24 A The conclusion that there was a high  
25 probability?

1 Q You told me --

2 A They're different things. A sample is a  
3 sample, but the --

4 Q Can you listen to the question --

5 A I'm listening.

6 Q -- please? Don't read too much into the  
7 question. Okay? You've reached the conclusion that  
8 there was likely defective Digitek in the marketplace,  
9 right?

10 A Yes.

11 Q You reached that conclusion through the  
12 regulatory documents, the 483s, the warning letters and  
13 a consent decree, correct?

14 A Yes.

15 Q You did not reach that conclusion by  
16 reading reports of scientists who had observed, measured  
17 or tested out-of-specification Digitek in the  
18 marketplace, correct?

19 A Correct.

20 MR. MORIARTY: Thank you. I'm done.

21 MS. DONAHUE: Are you ready?

22 THE WITNESS: Any time.

23 - - - - -

24 CROSS EXAMINATION

25



1 BY MS. DONAHUE:

2 Q Good afternoon, Mr. Farley.

3 A Yes, ma'am.

4 Q I introduced myself off the record. I'm  
5 Alicia Donahue. I'm with Shook, Hardy & Bacon in  
6 San Francisco and I represent the Mylan entities, as we  
7 call them, Mylan defendants, and UDL Labs in this case.

8 A Yes.

9 Q And one follow-up question to the  
10 deposition notice that I wanted to make sure we covered  
11 was in regard to that notice and the documents that you  
12 were requested to bring with you today pursuant to the  
13 second deposition notice, did you bring any new  
14 documents today to the deposition that weren't produced  
15 by you either physically or by virtue of the thumb drive  
16 at your original deposition back in July?

17 A My time log where I log in what day and  
18 how many hours I worked for Meghan.

19 Q That's been updated since your last  
20 deposition?

21 A It's last week. It just essentially is  
22 last week.

23 Q Could we get a copy of that?

24 A Yes. I have it on the thumb drive over  
25 there.

1 THE WITNESS: And, Meghan, I gave that to  
2 you last night.

3 A I mean -- excuse me. And I gave it to  
4 Meghan last night, yes.

5 MS. DONAHUE: Can we just agree, counsel  
6 that, you will --

7 A One is a time log and the other is an  
8 activity chart that says more what I did and the time  
9 log says when I did it so that it tells me I did what I  
10 was supposed to do and I know how much time to --

11 Q I appreciate that.

12 A -- how much time.

13 Q Thank you.

14 MS. DONAHUE: So, counsel, are we in  
15 agreement we can get a copy of that?

16 MS. CARTER: Yes.

17 MS. DONAHUE: Thank you.

18 BY MS. DONAHUE:

19 Q Okay. And now, very quickly, I believe,  
20 Mr. Farley, you in regard -- in response to one of  
21 Mr. Moriarty's earlier questions, I believe you  
22 testified that the purpose of your report in this case  
23 was to provide the opinions that you plan to render at  
24 trial in this case; is that correct?

25 A Yes.

1 Q Okay. And I went through your report  
2 pretty diligently and I didn't see any mention of any  
3 opinions in regard to either the Mylan defendants or UDL  
4 Labs.

5 A Yes.

6 Q Nowhere in that report did you opine that  
7 Mylan or UDL -- did you opine in any regard on their  
8 conduct in regard to distributing Digitek?

9 A Correct.

10 Q And nowhere in that report did you comment  
11 in regard to Mylan or UDL's conduct in regard to any  
12 testing that any of those entities may have done in  
13 regard to Digitek?

14 A Correct.

15 Q As you sit here today, Mr. Farley, do you  
16 intend to offer any opinions at the trial of these cases  
17 in regard to Mylan or UDL's conduct in relation to its  
18 distribution of Digitek?

19 A I do not intend to.

20 MS. DONAHUE: Thank you. That's all the  
21 questions I have.

22 - - - - -

23 CROSS EXAMINATION

24 BY MR. KERENSKY:

25 Q Sir, do you have -- excuse me. Sir, do

1 you have an opinion about whether or not it is probable,  
2 that being more likely true than not, that Actavis  
3 manufactured Digitek tablets that presented an  
4 unreasonable risk of serious bodily injury or death to  
5 consumers and that those tablets were actually  
6 distributed to the consuming public? Do you have an  
7 opinion about that based on reasonable probability and  
8 that being more likely true than not?

9 MR. MORIARTY: Objection.

10 Q Answer.

11 A I do have an opinion.

12 Q What is that opinion?

13 A It's my opinion -- and it is based on the  
14 483s and the warning letters and the consent decree --  
15 that in which the entire manufacturing and testing flow  
16 is shown to be completely inadequate and not in  
17 compliance with regulatory.

18 It is my opinion there's a very high  
19 likelihood that there may be what I call bad product out  
20 on the market and that consumers have a chance of being  
21 seriously injured.

22 MR. KERENSKY: Thank you. No further  
23 questions.

24 Any questions from you, Mr. Ernst? Did  
25 we start without him? Don?

1 MR. MORIARTY: It' snot my day to watch  
2 him.

3 MR. ERNST: Yes, I do. I've got some  
4 questions --

5 MR. KERENSKY: Go ahead.

6 MR. ERNST: -- if I can ask him.

7 MR. KERENSKY: Go ahead and ask him.  
8 It's your turn.

9 MR. ERNST: All right.

10 - - - - -

11 CROSS EXAMINATION

12 BY MR. ERNST:

13 Q Is it more likely true than untrue that  
14 Digitek tablets that presented a danger to consumers,  
15 including the risk of injury and death, were  
16 manufactured and placed into the stream of commerce by  
17 Actavis?

18 MR. MORIARTY: Objection, asked and  
19 answered not 120 seconds ago. Go ahead.

20 A In my opinion it is true what you said,  
21 yes.

22 Q Is it more likely true than untrue that  
23 Actavis failed to provide adequate quality control over  
24 the Digitek tablets that it manufactured?

25 A It is more likely true.

1           Q    Is it more likely true than not true that  
2 out-of-specification Digitek tablets were manufactured  
3 and distributed by Actavis?

4           A    It is more likely true. I believe that.

5           Q    Is it more likely true than untrue or more  
6 probably than not that Digitek tablets that presented a  
7 danger to consumers, including the risk of death, were  
8 actually placed into the stream of commerce and were  
9 received by consumers based upon the information and the  
10 documentation that you have reviewed to date?

11          A    In my opinion it is more likely true.

12          Q    Is it your opinion that based upon your  
13 training and experience that documents that you have  
14 reviewed, all of the reading material that you are aware  
15 of to date that Digitek tablets that were manufactured  
16 by Actavis presented a risk of harm to consumers?

17          A    Yes.

18          Q    And is it your opinion that because of  
19 this risk of harm to consumers that Digitek tablets were  
20 recalled?

21                   MR. MORIARTY: Objection.

22          A    Say again, please.

23          Q    Sure. Is it your opinion and is it more  
24 likely true than untrue that based upon the material  
25 that you have reviewed that the Digitek tablets were

1 recalled because they presented a danger to consumers,  
2 including the risk of death?

3 MR. MORIARTY: Objection.

4 A Yes.

5 MR. ERNST: Thank you. I have nothing  
6 else.

7 - - - - -

8 REDIRECT EXAMINATION

9 BY MR. MORIARTY:

10 Q I have a follow-up question for you.

11 A Yes, sir.

12 Q Now, you've heard Mr. Ernst over the  
13 telephone ask you some questions. Does his voice sound  
14 familiar?

15 A He was on speaker last night in here.

16 Q Okay. Did Mr. Ernst tell you that in his  
17 specific case tablets from his client's prescription  
18 were tested by NMS Laboratories and found to be within  
19 the Digitek specifications?

20 A No.

21 Q Okay. Is that kind of information  
22 important to you in rendering opinions in a case like  
23 this?

24 A All information such as that is important,  
25 some more or less.

1 MR. MORIARTY: Okay. Thank you. That's  
2 all I have.

3 MR. KERENSKY: Let's wrap it up. Head  
4 for the airport.

5 THE VIDEOGRAPHER: All right. That  
6 concludes the deposition of James Farley. It is  
7 12:59 p.m this is the end of Media Unit No. 4.  
8 Thank you.

9 (Off the record discussion was had.)

10 MR. MORIARTY: As you know from previous  
11 deposition experience you have the right, if you  
12 wish, to read and sign the transcript when it is  
13 prepared and distributed --

14 THE WITNESS: Yes.

15 MR. MORIARTY: -- to make sure that she  
16 typed complicated words properly, spelled them,  
17 got everything you said, et cetera. Okay?

18 THE WITNESS: Yes.

19 MR. MORIARTY: Or you can waive that  
20 right, trusting that she's an excellent court  
21 reporter with obvious long-term experience in this  
22 and never had to stop us to ask us anything. It's  
23 up to you.

24 THE WITNESS: With all due respect to  
25 Angela, I would like to read it.



1 MR. MORIARTY: Fine.

2 (The proceedings were concluded at 1:00 p.m.)

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1 CERTIFICATE

2

3 GEORGIA:

4 CHATHAM COUNTY:

5

6 I, Angela S. Garrett, Certified Shorthand  
7 Reporter for the State of Georgia, do hereby certify:

8 That the foregoing deposition was taken before  
9 me on the date and at the time and location stated on  
10 Page 1 of this transcript; that the witness was duly  
11 sworn to testify to the truth, the whole truth, and  
12 nothing but the truth; that the testimony of the witness  
13 and all objections made at the time of the examination  
14 were recorded stenographically by me and were thereafter  
15 transcribed by computer-aided transcription; that the  
16 foregoing deposition, as typed, is a true, accurate, and  
17 complete record of the testimony of the witness and of  
18 all objections made at the time of the examination.

19 I further certify that I am neither related to  
20 nor counsel for any party to the cause pending or  
21 interested in the events thereof.

22

23

24

25

1                   Witness my hand, I have hereunto affixed my  
2   official seal this 24th day of January, 2011, at  
3   Savannah, Chatham County, Georgia.

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Angela S. Garrett, CSR, RPR

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## 1 D I S C L O S U R E

2 Pursuant to Article 8.B. of the Rules and  
3 Regulations of the Board of Court Reporting of the  
4 Judicial Council of Georgia, I make the following  
5 disclosure:

6 I am a Georgia Certified Court Reporter. I was  
7 contacted by my office of McKee Court Reporting, Inc.,  
8 to provide court reporting services for this deposition.

9 I will not be taking this deposition under any  
10 contract that is prohibited by O.C.G.A. 15-14-37(a) and  
11 (b).

12 I have no contract/agreement to provide reporting  
13 services with any party to the case, any counsel in the  
14 case or any reporter or reporting agency from whom a  
15 referral might have been made to cover the deposition.

16 I will charge its usual and customary rates to all  
17 parties in the case, and a financial discount will not  
18 be given to any party to this litigation.

19

20

21

22

23 \_\_\_\_\_ Date: January 24, 2011

24 Angela S. Garrett  
25 RPR, CCR-B2407

25